

US3122083 (Prod: M3 Wake Research, Inc - M3 Wake)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:21:06

All time stamps listed in this document are displayed in GMT

US3122083

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

[Participant ID](#)

US3122083

[mRNA-1273-P301 Completion Guidelines](#)

US3122083

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3122083

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3122083

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Date of Informed Consent (*dd MMM yyyy*) 28 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3122083

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 20:54:07

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 20:54:07

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 20:54:07

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Condition	ASTHMA (ASYMPTOMATIC)
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3122083

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	PARTIAL HYSTERECTOMY - BIRTH CONTROL
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3122083

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	FELINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1968
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1968
Start Year (derived)	1968
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	LABRAL TEAR - LEFT HIP
Start date (dd MMM yyyy)	UN OCT 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2016
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2015
Start Year (derived)	2015
Stop Month and Year (derived)	FEB 2016
Stop Year (derived)	2016

US3122083

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	CHEILECTOMY - RIGHT BIG TOE
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3122083

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	CHEILECTOMY - LEFT BIG TOE
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3122083

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	LABRAL TEAR REPAIR SURGERY - LEFT
Start date (dd MMM yyyy)	UN FEB 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2016
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2016
Start Year (derived)	2016
Stop Month and Year (derived)	FEB 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	BILATERAL LASIK SURGERY - VISION CORRECTION
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Condition	HERPES SIMPLEX VIRUS - VAGINAL
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3122083

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 14:12
Height (xxx.x)	62 in
Weight (xxx.x)	193.2 lb
BMI (xxx.x)	35.41063 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 20:54:07

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Date of assessment (*dd MMM yyyy*) 28 JUL 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 2011

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:07

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

What was the date of randomization? (dd MMM yyyy) 28 JUL 2020

What was the participant's randomization number? 142138

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☒
 No ☐

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐
 No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐
 No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐
 No ☒

Liver Disease Yes ☐
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 14:12
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	16:26 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 16:26
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 JUL 2020

What was the treatment time? (00:00-23:59) 15:51 (24 HR)

Treatment Date and Time (derived) 28 JUL 2020 15:51

Which arm was used to give treatment? Left Arm ☐ Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JUL 2020

Collection time (00:00-23:59)

15:21 (24 HR)

Collection date and time (derived)

28 JUL 2020 15:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Collection date (dd MMM yyyy)			28 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:33	28 JUL 2020 15:33
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐
No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 JUL 2020 16:11

PC Close Date & Time

28 JUL 2020 18:41

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	28 JUL 2020 20:11
PC Open Date & Time	28 JUL 2020 19:36
PC Close Date & Time	29 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

29 JUL 2020 13:00

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

30 JUL 2020 12:25

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

31 JUL 2020 17:18

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

01 AUG 2020 23:01

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

02 AUG 2020 15:49

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

03 AUG 2020 12:09

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 JUL 2020 16:11

PC Close Date & Time

28 JUL 2020 18:41

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 JUL 2020 20:08

PC Open Date & Time

28 JUL 2020 19:36

PC Close Date & Time

29 JUL 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 13:00

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 12:26

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 17:18

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 23:01

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 15:50

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 12:09

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 JUL 2020 16:11

PC Close Date & Time

28 JUL 2020 18:41

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 20:07
PC Open Date & Time	28 JUL 2020 19:36
PC Close Date & Time	29 JUL 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 13:01
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 12:26
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 17:18
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

62 of 2201

EAB) (1725)

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 23:02
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 15:50
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 12:09
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

04 AUG 2020 12:00

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

05 AUG 2020 13:18

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 AUG 2020 00:02

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 AUG 2020 12:00
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 AUG 2020 13:18
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 AUG 2020 00:02
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3122083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:20
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:20
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3122083

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 AUG 2020

What was the treatment time? (00:00-23:59) 14:43 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 14:43

Which arm was used to give treatment? Left Arm ☐
Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3122083

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	26 AUG 2020
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Collection time (00:00-23:59)	14:14 (24 HR)
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Collection date and time (derived)	26 AUG 2020 14:14
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US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:21	26 AUG 2020 14:21
Nasopharyngeal Swab 2	No		

US3122083

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

26 AUG 2020 15:12

PC Open Date & Time

26 AUG 2020 15:03

PC Close Date & Time

26 AUG 2020 17:33

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	27 AUG 2020 08:49
PC Open Date & Time	26 AUG 2020 18:28
PC Close Date & Time	27 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

27 AUG 2020 12:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

28 AUG 2020 12:30

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

29 AUG 2020 12:56

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

30 AUG 2020 14:27

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

31 AUG 2020 12:15

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

01 SEP 2020 12:42

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 15:09

PC Open Date & Time

26 AUG 2020 15:03

PC Close Date & Time

26 AUG 2020 17:33

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 08:50

PC Open Date & Time

26 AUG 2020 18:28

PC Close Date & Time

27 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 12:13

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:57

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 14:28

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:16

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:42

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 15:10
PC Open Date & Time	26 AUG 2020 15:03
PC Close Date & Time	26 AUG 2020 17:33

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 08:50
PC Open Date & Time	26 AUG 2020 18:28
PC Close Date & Time	27 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:13
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 14:28
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:16
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:42
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3122083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:08

Generated On: 09 Jun 2021 15:21:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:54:08

Generated On: 09 Jun 2021 15:21:06

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3122083

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:08

Generated On: 09 Jun 2021 15:21:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3122083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:54:08

Generated On: 09 Jun 2021 15:21:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

08:24 (24 HR)

Collection date and time (derived)

25 SEP 2020 08:24

US3122083

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:08

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 SEP 2020 00:32:59
Patient Cloud Open Date & Time	27 SEP 2020 00:01
Patient Cloud Close Date & Time	01 OCT 2020 23:59

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

04 OCT 2020 09:19:52

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 78

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

11 OCT 2020 01:48:24

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 92

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 OCT 2020 00:10:25

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 99

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

01 NOV 2020 00:02:38

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 106

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

08 NOV 2020 07:48:45

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 113

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 NOV 2020 00:05:25

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	26 NOV 2020 00:01
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Patient Cloud Close Date & Time	30 NOV 2020 23:59
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US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 DEC 2020 06:10:53

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 DEC 2020 00:04:50

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 145

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 DEC 2020 07:13:54

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 DEC 2020 00:01:23

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

31 DEC 2020 00:02:02

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 08:51:38
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

14 JAN 2021 00:01:27

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 180

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

21 JAN 2021 00:01:36

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

28 JAN 2021 00:01:25

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 194

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

04 FEB 2021 00:01:47

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 00:22:22
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

18 FEB 2021 02:34:13

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 FEB 2021 05:22:27

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

04 MAR 2021 00:02:20

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

11 MAR 2021 09:27:09

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 236

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

18 MAR 2021 17:49:16

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 MAR 2021 01:43:03

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

01 APR 2021 00:36:10

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

08 APR 2021 06:10:52

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 264

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 APR 2021 00:46:16

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

22 APR 2021 00:10:24

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

29 APR 2021 00:12:29

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	01 JUL 2021 00:01
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Patient Cloud Close Date & Time	05 JUL 2021 23:59
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US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 AUG 2021 00:01
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Patient Cloud Close Date & Time	09 AUG 2021 23:59
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US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	26 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	23 SEP 2021 00:01
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Patient Cloud Close Date & Time	27 SEP 2021 23:59
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US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	24 MAR 2022 00:01
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Patient Cloud Close Date & Time	28 MAR 2022 23:59
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US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	11 AUG 2022 00:01
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Patient Cloud Close Date & Time	15 AUG 2022 23:59
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US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	18 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3122083

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:21:06

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	01 MAR 2021 12:58:03

US3122083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

PATIENT WAS INITIALLY
CONTACTED 12NOV2020 BUT
REQUESTED LATER CALL

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 13:54:53

Generated On: 09 Jun 2021 15:21:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:40 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 09:40
Temperature (<i>xxx.x</i>)	36.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3122083

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3122083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3122083

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 18:31:04

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 18:31:04

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:11:16

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:11:16

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3122083

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:21:06

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3122083

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:21:06

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	12 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Height	
Weight	
BMI (xxx.x)	

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:20
Temperature (xxx.x)	95.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	11:37 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 11:37
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 10:59 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 10:59

Which arm was used to give treatment? Left Arm ☐ Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

10:51 (24 HR)

Collection date and time (derived)

12 JAN 2021 10:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	10:54
Collection Date and Time (derived)	12 JAN 2021 10:54

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3122083

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 FEB 2021
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 09:40
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3122083

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3122083

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 10 FEB 2021

What was the treatment time? (00:00-23:59) 10:29 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 10:29

Which arm was used to give treatment? Left Arm ☐ Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3122083

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122083

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:07

Generated On: 09 Jun 2021 15:21:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122083

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:05 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 09:05
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 18:58:01

Generated On: 09 Jun 2021 15:21:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	09:10 (24 HR)
Collection date and time (derived)	15 MAR 2021 09:10

US3122083

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Apr 2021 19:41:42

Generated On: 09 Jun 2021 15:21:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:21:06

AEID

Adverse event

SINUS INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:21:06

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:21:06

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 JUL 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	29 JUL 2020 00:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	05 AUG 2020
End time (00:00-23:59)	23:59 (24 HR)
AE End Date and Time (derived)	05 AUG 2020 23:59
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:21:06

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:21:06

AEID	USA-US063-2021-MRNA-1273-P30 1000003
Adverse event	ANAPHYLACTIC REACTION TO STEROID SHOT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:21:06

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 5000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

Name of Medication ADVAIR 100/50

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☒
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2002	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

Name of Medication XOPENEX

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☒
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

Name of Medication VALTREX

Prophylaxis Yes ☐
No ☒

Indication HERPES TYPE 2

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC INJECTIONS

Dose per administration 25

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☒
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

380 of 2201

EAB) (1725)

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Mar 2021 17:22:38

Generated On: 09 Jun 2021 15:21:06

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3122083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 20:54:06

Generated On: 09 Jun 2021 15:21:06

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3122083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 30 Apr 2021 19:28:26

Generated On: 09 Jun 2021 15:21:06

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 AUG 2020	SUBJECT USED NETI POT FOR TREATMENT OF SINUS INFECTION	Adverse Event	

US3122083

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:21:06

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3122083

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:21:06

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:21:06

SAEID	USA-US063-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 16:57:10

Generated On: 09 Jun 2021 15:21:06

SAEID	USA-US063-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WAYNE
Investigator's Last Name	HARPER
Site Address: Street	3100 DURALEIGH RD
Site Address: City	RALEIGH
Site Address: State	NC
Site Address: Postal Code	27612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	26/APR/2021 12:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3122083 (Prod: M3 Wake Research, Inc - M3 Wake)

US3122083

Form: Participant Creation

Generated On: 09 Jun 2021 15:21:06

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'US3122083'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:04:31

US3122083

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:33

US3122083

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:04:32

US3122083

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:33

US3122083

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'SCRN'	System	28 Jul 2020 22:42:33

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:04:33

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '57'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'YEARS'	System	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '57'	System	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:42:47

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jul 2020'	System	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2020'	System	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:04

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:04:32

US3122083

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'I'	System	28 Jul 2020 22:43:10

US3122083

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:21:06

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:10

US3122083

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:21:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:30:49

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 20:16:15
User coded data point as Term Coded data point by User (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 20:16:15
Data point term sent to Coder	System	31 Jul 2020 16:36:21
User entered 'Asthma (asymptomatic)'	Brad Killebrew (b) (4)	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 1968'	Brad Killebrew (b) (4)	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 1968'	System	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '1968'	System	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:35:34

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:37:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:37:03
Data point term sent to Coder	System	31 Jul 2020 16:36:21
User entered 'Hiatal Hernia'	Brad Killebrew (b) (4)	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 2018'	Brad Killebrew (b) (4)	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2018'	System	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2018'	System	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:36:15

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Subtotal hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 09:13:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 09:13:50
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:37:33
Data point term sent to Coder	System	17 Sep 2020 17:59:35
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	17 Sep 2020 17:58:49
Coding entries removed.	Brad Killebrew (b) (4)	17 Sep 2020 17:58:45
User entered 'PARTIAL HYSTERECTOMY - birth control' reason for change: New Information	Brad Killebrew (b) (4)	17 Sep 2020 17:58:45
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 06:39:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Subtotal hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 16:47:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 16:47:06
Data point term sent to Coder	System	31 Jul 2020 16:46:32
Coding entries removed.	Brad Killebrew (b) (4)	31 Jul 2020 16:45:46

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
User entered 'Partial HYSTERECTOMY' reason for change: New Information	Brad Killebrew (b) (4)	31 Jul 2020 16:45:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:39:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:39:07
Data point term sent to Coder	System	31 Jul 2020 16:37:24
User entered 'Hysterectomy'	Brad Killebrew (b) (4)	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 2011'	Brad Killebrew (b) (4)	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 2011'	Brad Killebrew (b) (4)	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2011'	System	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2011'	System	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2011'	System	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2011'	System	31 Jul 2020 16:36:53

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:39:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:39:07
Data point term sent to Coder	System	31 Jul 2020 16:37:22
User entered 'Anxiety'	Brad Killebrew (b) (4)	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 1980'	Brad Killebrew (b) (4)	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 1980'	System	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '1980'	System	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:37:18

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:39:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:39:07
Data point term sent to Coder	System	31 Jul 2020 16:38:24
User entered 'Depression'	Brad Killebrew (b) (4)	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 1980'	Brad Killebrew (b) (4)	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 1980'	System	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '1980'	System	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:37:57

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergic to cats - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 21:06:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 21:06:13
Data point term sent to Coder	System	31 Jul 2020 16:38:24
User entered 'Feline Allergy'	Brad Killebrew (b) (4)	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 1968'	Brad Killebrew (b) (4)	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 1968'	System	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '1968'	System	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:38:15

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:40:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:40:11
Data point term sent to Coder	System	31 Jul 2020 16:39:25
User entered 'Seasonal Allergies'	Brad Killebrew (b) (4)	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 1968'	Brad Killebrew (b) (4)	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 1968'	System	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '1968'	System	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	31 Jul 2020 16:38:50

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Cartilage injury, LLT: Cartilage injury - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:57:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:57:48
Data point term sent to Coder	System	31 Jul 2020 16:40:26
User entered 'Labral Tear - Left Hip'	Brad Killebrew (b) (4)	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN Oct 2015'	Brad Killebrew (b) (4)	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN Feb 2016'	Brad Killebrew (b) (4)	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Oct 2015'	System	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2015'	System	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Feb 2016'	System	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2016'	System	31 Jul 2020 16:39:30

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Cheilectomy, LLT: Cheilectomy - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 20:40:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 20:40:07
Data point term sent to Coder	System	31 Jul 2020 16:42:27
User entered 'Cheilectomy - Right Big Toe'	Brad Killebrew (b) (4)	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 2003'	Brad Killebrew (b) (4)	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Jul 2020 16:42:32
User entered 'No (N)' reason for change: Data Entry Error	System	31 Jul 2020 16:42:32
User opened query 'Data is required. Please complete.' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 16:42:32
User entered empty.	System	31 Jul 2020 16:42:14
	Brad Killebrew (b) (4)	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 2003'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2003'	System	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2003'	System	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2003'	System	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2003'	System	31 Jul 2020 16:42:14

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Cheilectomy, LLT: Cheilectomy - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 20:38:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Jul 2020 20:38:13
Data point term sent to Coder	System	31 Jul 2020 16:45:31
User entered 'Cheilectomy - Left Big Toe'	Brad Killebrew (b) (4)	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 2005'	Brad Killebrew (b) (4)	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 2005'	Brad Killebrew (b) (4)	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2005'	System	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2005'	System	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2005'	System	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2005'	System	31 Jul 2020 16:45:05

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:49:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 16:49:04
Data point term sent to Coder	System	31 Jul 2020 16:48:35
User entered 'Tonsillectomy'	Brad Killebrew (b) (4)	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'UN UNK 1970'	Brad Killebrew (b) (4)	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'un UNK 1970'	Brad Killebrew (b) (4)	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 1970'	System	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '1970'	System	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 1970'	System	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '1970'	System	31 Jul 2020 16:47:32

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Cartilage therapeutic procedures, PT: Chondroplasty, LLT: Cartilage repair - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 12:41:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 12:41:59
User closed query 'Per DM CLR Please specify the laterality of LABRAL TEAR REPAIR SURGERY(left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.	(b) (4), (b) (6)	18 Sep 2020 13:37:56
' (Site from DM).		
Data point term sent to Coder	System	17 Sep 2020 17:57:31
Query 'Per DM CLR Please specify the laterality of LABRAL TEAR REPAIR SURGERY(left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.	Brad Killebrew (b) (4)	17 Sep 2020 17:57:17
' answered with 'updated' (Site from DM).		
Coding entries removed.	Brad Killebrew (b) (4)	17 Sep 2020 17:57:12
User entered 'LABRAL TEAR REPAIR SURGERY - left' reason for change: Data Entry Error	Brad Killebrew (b) (4)	17 Sep 2020 17:57:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Cartilage therapeutic procedures, PT: Chondroplasty, LLT: Cartilage repair - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 13:05:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 13:05:42
User opened query 'Per DM CLR Please specify the laterality of LABRAL TEAR REPAIR SURGERY(left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 05:53:22

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	31 Jul 2020 16:48:35
User entered 'Labral Tear Repair Surgery'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'un Feb 2016'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'un Feb 2016'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Feb 2016'	System	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2016'	System	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Feb 2016'	System	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2016'	System	31 Jul 2020 16:48:16

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 06:06:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 06:06:37
User closed query 'er DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:38:35
User closed query 'Per DM CLR: Please specify the laterality of the EYE LASIK SURGERY (left, right,both eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		18 Sep 2020 13:38:07
Data point term sent to Coder	System	17 Sep 2020 17:58:32
Query 'er DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	17 Sep 2020 17:58:07
User entered 'BILATERAL LASIK SURGERY - vision correction' reason for change: Data Entry Error	Brad Killebrew (b) (4)	17 Sep 2020 17:58:02
Query 'Per DM CLR: Please specify the laterality of the EYE LASIK SURGERY (left, right,both eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	17 Sep 2020 17:57:53
Coding entries removed.	Brad Killebrew (b) (4)	17 Sep 2020 17:57:48
User entered 'bilateral LASIK SURGERY' reason for change: Data Entry Error	Brad Killebrew (b) (4)	17 Sep 2020 17:57:48

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

Condition

Audit	User	Time (GMT)
User opened query 'er DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 05:40:31
User opened query 'Per DM CLR: Please specify the laterality of the EYE LASIK SURGERY (left, right,both eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		05 Sep 2020 05:40:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 16:18:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 16:18:02
Data point term sent to Coder	System	31 Jul 2020 16:49:37
User entered 'Lasik Surgery'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'un UNK 2002'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'un UNK 2002'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2002'	System	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2002'	System	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2002'	System	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2002'	System	31 Jul 2020 16:48:59

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes simplex, LLT: Genital herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 13:41:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 13:41:51
Data point term sent to Coder	System	17 Sep 2020 17:53:22
User entered 'herpes simplex virus - vaginal'	Brad Killebrew (b) (4)	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'un UNK 2010'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'Jan 2010'	System	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '2010'	System	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:21:06

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered empty.	System	17 Sep 2020 17:53:08

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '14:12'	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered '28 Jul 2020 14:12'	System	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '62' in	(b) (4)	
	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25
DataPoint set to visible.	System	28 Jul 2020 22:43:10

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '193.2' lb	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:01:25
DataPoint set to visible.	System	28 Jul 2020 22:43:10

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
Amendment Manager: User entered '35.41063'	System	16 Sep 2020 23:37:34
User entered '35.4'	System	31 Jul 2020 17:01:25
DataPoint set to visible.	System	28 Jul 2020 22:43:10

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'kg/m2'	System	31 Jul 2020 17:01:25
DataPoint set to visible.	System	28 Jul 2020 22:43:10

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:29
User entered '98.9' F	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 01:56:24
Query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	08 Sep 2020 17:13:38
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 17:13:33
User opened query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 11:09:19
User entered 'Other (Other)' reason for change: Data Entry Error	Leah Corts (b) (4)	18 Aug 2020 13:42:29
User entered 'Oral (Oral)'	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:29
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:29
User entered '73'	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'bpm'	System	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:29
User entered '18'	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'breaths/min'	System	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:29
User entered '132'	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'mmHg'	System	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:29
User entered '71'	Brad Killebrew (b) (4)	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User entered 'mmHg'	System	31 Jul 2020 17:01:25

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 21:50:59

US3122083

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59

US3122083

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:02:19

US3122083

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:09:19
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:54:21
User entered '28 Jul 2020'	Brad Killebrew (b) (4)	31 Jul 2020 17:02:19

US3122083

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	Brad Killebrew (b) (4)	31 Jul 2020 17:14:17

US3122083

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:21:06

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:14:17

US3122083

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:21:06

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Surgically sterile (SURGICALLY STERILE)'	Brad Killebrew (b) (4)	31 Jul 2020 17:14:17

US3122083

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:21:06

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:14:17

US3122083

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:21:06

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'un UNK 2011'	Brad Killebrew (b) (4)	31 Jul 2020 17:14:17

US3122083

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:21:06

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 17:14:17

US3122083

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:21:06

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:14:17

US3122083

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:21:06

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 17:14:17

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Retired'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'I'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'I'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:50:59
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:21:55

US3122083

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:23

US3122083

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:23

US3122083

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:43:23

US3122083

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'VISIT1'	System	28 Jul 2020 22:43:23

US3122083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:06

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:04:34

US3122083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:06

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:09:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:09:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 19:04:34
User entered '142138' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 19:04:34

US3122083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:06

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	28 Jul 2020 19:04:34

US3122083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:06

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:26:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Leah Corts (b) (4)	28 Aug 2020 19:26:06
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 22:45:16
User entered empty.	(b) (4), (b) (6)	28 Jul 2020 22:45:16

US3122083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:06

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:16

US3122083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:06

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:16

US3122083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:06

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:16

US3122083

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:16

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:00
User entered '62' in	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:00
User entered '193.2' lb	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:00
User entered '62' in	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:00
User entered '193.2' lb	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User accepted default value 'Pre-Dose (PREDOSE)'	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '14:12'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '28 Jul 2020 14:12'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '98.9' F	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (Oral)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '73'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'bpm'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '18'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'breaths/min'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '132'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'mmHg'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '71'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'mmHg'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:00
User entered '62' in	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	18 Aug 2020 13:42:00
User entered '193.2' lb	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User accepted default value 'Post-Dose (POSTDOSE)'	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Aug 2020 19:33:57
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Correct as is ' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 17:24:07
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		31 Jul 2020 17:23:55
User entered '16:26'	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '28 Jul 2020 16:26'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '98.6' F	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (Oral)'	Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '66'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'bpm'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '18'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'breaths/min'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '125'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'mmHg'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '80'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'mmHg'	System	31 Jul 2020 17:23:55

US3122083

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:24:28

US3122083

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:24:28

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '15:51'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '28 Jul 2020 15:51'	System	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'ONCE'	System	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 22:45:44

US3122083

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:40:15

US3122083

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:40:15

US3122083

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '15:21'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:40:15

US3122083

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '28 Jul 2020 15:21'	System	31 Jul 2020 17:40:15

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '28 Jul 2020'	Brad Killebrew (b) (4)	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brad Killebrew (b) (4)	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '15:33'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '28 Jul 2020 15:33'	System	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brad Killebrew (b) (4)	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Brad Killebrew (b) (4)	31 Jul 2020 17:41:00
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 19:23:40
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered with 'corrected' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 17:40:58
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	31 Jul 2020 17:40:43
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered empty.	System	31 Jul 2020 17:40:43

US3122083

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 23:00:17

US3122083

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '1'	System	07 Aug 2020 23:00:17

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 16:11'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 18:41'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:10:28', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '387a07a7-d64d-47ff-8a71-beca97a481b9' User entered 'Yes (Y)'	System	29 Jul 2020 00:11:05
	System	29 Jul 2020 00:11:05

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:10:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '387a07a7-d64d-47ff-8a71-beca97a481b9' User entered '97.1'	System	29 Jul 2020 00:11:05
	System	29 Jul 2020 00:11:05

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:10:57', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '387a07a7-d64d-47ff-8a71-beca97a481b9' User entered 'No (N)'	System	29 Jul 2020 00:11:05
	System	29 Jul 2020 00:11:05

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:11:01', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '387a07a7-d64d-47ff-8a71-beca97a481b9' User entered '28 Jul 2020 20:11'	System	29 Jul 2020 00:11:05
	System	29 Jul 2020 00:11:05

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 19:36'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 2'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T12:59:54', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dd5d8b29-a089-497a-960b-14958ca64a8d' User entered 'Yes (Y)'	System	29 Jul 2020 17:00:08
	System	29 Jul 2020 17:00:08

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T12:59:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dd5d8b29-a089-497a-960b-14958ca64a8d' User entered '97.3'	System	29 Jul 2020 17:00:08
	System	29 Jul 2020 17:00:08

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:00:02', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dd5d8b29-a089-497a-960b-14958ca64a8d' User entered 'No (N)'	System	29 Jul 2020 17:00:08
	System	29 Jul 2020 17:00:08

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:00:06', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dd5d8b29-a089-497a-960b-14958ca64a8d' User entered '29 Jul 2020 13:00'	System	29 Jul 2020 17:00:08
	System	29 Jul 2020 17:00:08

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 3'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:25:36', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f682517a-0d11-40e2-8206-21c238cffd31' User entered 'Yes (Y)'	System	30 Jul 2020 16:25:51
	System	30 Jul 2020 16:25:51

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:25:40', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f682517a-0d11-40e2-8206-21c238cffd31' User entered '96.3'	System	30 Jul 2020 16:25:51
	System	30 Jul 2020 16:25:51

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:25:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f682517a-0d11-40e2-8206-21c238cffd31' User entered 'No (N)'	System	30 Jul 2020 16:25:51
	System	30 Jul 2020 16:25:51

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:25:49', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f682517a-0d11-40e2-8206-21c238cffd31' User entered '30 Jul 2020 12:25'	System	30 Jul 2020 16:25:51
	System	30 Jul 2020 16:25:51

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 4'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:17:49', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5d086777-17d0-4ef0-93f6-20a4d1880c8d' User entered 'Yes (Y)'	System	31 Jul 2020 21:18:03
	System	31 Jul 2020 21:18:03

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:17:56', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5d086777-17d0-4ef0-93f6-20a4d1880c8d' User entered '96.7'	System	31 Jul 2020 21:18:03
	System	31 Jul 2020 21:18:03

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:17:58', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5d086777-17d0-4ef0-93f6-20a4d1880c8d' User entered 'No (N)'	System	31 Jul 2020 21:18:03
	System	31 Jul 2020 21:18:03

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:01', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5d086777-17d0-4ef0-93f6-20a4d1880c8d' User entered '31 Jul 2020 17:18'	System	31 Jul 2020 21:18:03
	System	31 Jul 2020 21:18:03

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 5'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:10', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '312dc73b-d68f-414b-ad96-51b6a24b152b' User entered 'Yes (Y)'	System	02 Aug 2020 03:01:26
	System	02 Aug 2020 03:01:26

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:15', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '312dc73b-d68f-414b-ad96-51b6a24b152b' User entered '97.5'	System	02 Aug 2020 03:01:26
	System	02 Aug 2020 03:01:26

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '312dc73b-d68f-414b-ad96-51b6a24b152b' User entered 'No (N)'	System	02 Aug 2020 03:01:26
	System	02 Aug 2020 03:01:26

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '312dc73b-d68f-414b-ad96-51b6a24b152b' User entered '01 Aug 2020 23:01'	System	02 Aug 2020 03:01:26
	System	02 Aug 2020 03:01:26

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 6'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:48:56', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '51e60c9b-293d-4463-8fb4-2456a6f174f0' User entered 'Yes (Y)'	System	02 Aug 2020 19:49:33
	System	02 Aug 2020 19:49:33

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:49:26', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '51e60c9b-293d-4463-8fb4-2456a6f174f0' User entered '98.4'	System	02 Aug 2020 19:49:33
	System	02 Aug 2020 19:49:33

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:49:28', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '51e60c9b-293d-4463-8fb4-2456a6f174f0'	System	02 Aug 2020 19:49:33
User entered 'No (N)'	System	02 Aug 2020 19:49:33

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:49:31', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '51e60c9b-293d-4463-8fb4-2456a6f174f0'	System	02 Aug 2020 19:49:33
User entered '02 Aug 2020 15:49'	System	02 Aug 2020 19:49:33

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 7'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:02', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fa2dda08-e670-4b8d-bd5d-315a5b20fb22' User entered 'Yes (Y)'	System	03 Aug 2020 16:09:13
	System	03 Aug 2020 16:09:13

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:07', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fa2dda08-e670-4b8d-bd5d-315a5b20fb22' User entered '98.6'	System	03 Aug 2020 16:09:13
	System	03 Aug 2020 16:09:13

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:09', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fa2dda08-e670-4b8d-bd5d-315a5b20fb22'	System	03 Aug 2020 16:09:13
User entered 'No (N)'	System	03 Aug 2020 16:09:13

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:11', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fa2dda08-e670-4b8d-bd5d-315a5b20fb22'	System	03 Aug 2020 16:09:13
User entered '03 Aug 2020 12:09'	System	03 Aug 2020 16:09:13

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 16:11'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 18:41'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:07:39', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '63ee2506-0a71-4c27-ac9e-7ce3e998ff94'	System	29 Jul 2020 00:08:43
User entered 'None (1)'	System	29 Jul 2020 00:08:43

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:07:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '63ee2506-0a71-4c27-ac9e-7ce3e998ff94'	System	29 Jul 2020 00:08:43
User entered 'No (N)'	System	29 Jul 2020 00:08:43

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:08:25', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '63ee2506-0a71-4c27-ac9e-7ce3e998ff94' User entered 'No (N)'	System	29 Jul 2020 00:08:43
	System	29 Jul 2020 00:08:43

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:08:36', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '63ee2506-0a71-4c27-ac9e-7ce3e998ff94'	System	29 Jul 2020 00:08:43
User entered 'None (1)'	System	29 Jul 2020 00:08:43

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:08:41', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '63ee2506-0a71-4c27-ac9e-7ce3e998ff94' User entered '28 Jul 2020 20:08'	System	29 Jul 2020 00:08:43
	System	29 Jul 2020 00:08:43

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 19:36'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 2'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:00:13', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '368a6769-5de9-461e-ada8-ddb7c77cc951'	System	29 Jul 2020 17:00:40
User entered 'None (1)'	System	29 Jul 2020 17:00:40

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:00:21', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '368a6769-5de9-461e-ada8-ddb7c77cc951'	System	29 Jul 2020 17:00:40
User entered 'No (N)'	System	29 Jul 2020 17:00:40

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:00:26', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '368a6769-5de9-461e-ada8-ddb7c77cc951'	System	29 Jul 2020 17:00:40
User entered 'No (N)'	System	29 Jul 2020 17:00:40

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:00:32', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '368a6769-5de9-461e-ada8-ddb7c77cc951'	System	29 Jul 2020 17:00:40
User entered 'None (1)'	System	29 Jul 2020 17:00:40

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:00:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '368a6769-5de9-461e-ada8-ddb7c77cc951' User entered '29 Jul 2020 13:00'	System	29 Jul 2020 17:00:40
	System	29 Jul 2020 17:00:40

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 3'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:25:53', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '980d34d1-26ce-4090-a72d-43be900aac66'	System	30 Jul 2020 16:26:16
User entered 'None (1)'	System	30 Jul 2020 16:26:16

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:25:56', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '980d34d1-26ce-4090-a72d-43be900aac66' User entered 'No (N)'	System	30 Jul 2020 16:26:16
	System	30 Jul 2020 16:26:16

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:02', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '980d34d1-26ce-4090-a72d-43be900aac66' User entered 'No (N)'	System	30 Jul 2020 16:26:16
	System	30 Jul 2020 16:26:16

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:08', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '980d34d1-26ce-4090-a72d-43be900aac66' User entered 'None (1)'	System	30 Jul 2020 16:26:16
	System	30 Jul 2020 16:26:16

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:10', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '980d34d1-26ce-4090-a72d-43be900aac66' User entered '30 Jul 2020 12:26'	System	30 Jul 2020 16:26:16
	System	30 Jul 2020 16:26:16

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 4'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:06', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'd5b808f0-7e0c-406c-8828-417846f52ab7' User entered 'None (1)'	System	31 Jul 2020 21:18:23
	System	31 Jul 2020 21:18:23

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'd5b808f0-7e0c-406c-8828-417846f52ab7' User entered 'No (N)'	System	31 Jul 2020 21:18:23
	System	31 Jul 2020 21:18:23

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:14', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'd5b808f0-7e0c-406c-8828-417846f52ab7' User entered 'No (N)'	System	31 Jul 2020 21:18:23
	System	31 Jul 2020 21:18:23

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:16', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'd5b808f0-7e0c-406c-8828-417846f52ab7' User entered 'None (1)'	System	31 Jul 2020 21:18:23
	System	31 Jul 2020 21:18:23

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'd5b808f0-7e0c-406c-8828-417846f52ab7'	System	31 Jul 2020 21:18:23
User entered '31 Jul 2020 17:18'	System	31 Jul 2020 21:18:23

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 5'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:26', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a1e91d2f-4c90-4f08-a12d-323491a3e6c1' User entered 'None (1)'	System	02 Aug 2020 03:01:38
	System	02 Aug 2020 03:01:38

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:29', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a1e91d2f-4c90-4f08-a12d-323491a3e6c1' User entered 'No (N)'	System	02 Aug 2020 03:01:38
	System	02 Aug 2020 03:01:38

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:32', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a1e91d2f-4c90-4f08-a12d-323491a3e6c1' User entered 'No (N)'	System	02 Aug 2020 03:01:38
	System	02 Aug 2020 03:01:38

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:34', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a1e91d2f-4c90-4f08-a12d-323491a3e6c1' User entered 'None (1)'	System	02 Aug 2020 03:01:38
	System	02 Aug 2020 03:01:38

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:37', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a1e91d2f-4c90-4f08-a12d-323491a3e6c1' User entered '01 Aug 2020 23:01'	System	02 Aug 2020 03:01:38
	System	02 Aug 2020 03:01:38

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 6'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:03', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8c35ec68-8e46-451d-9dc8-446b28a5197f'	System	02 Aug 2020 19:50:17
User entered 'None (1)'	System	02 Aug 2020 19:50:17

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:05', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8c35ec68-8e46-451d-9dc8-446b28a5197f' User entered 'No (N)'	System	02 Aug 2020 19:50:17
	System	02 Aug 2020 19:50:17

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:08', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8c35ec68-8e46-451d-9dc8-446b28a5197f' User entered 'No (N)'	System	02 Aug 2020 19:50:17
	System	02 Aug 2020 19:50:17

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8c35ec68-8e46-451d-9dc8-446b28a5197f' User entered 'None (1)'	System	02 Aug 2020 19:50:17
	System	02 Aug 2020 19:50:17

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:15', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8c35ec68-8e46-451d-9dc8-446b28a5197f' User entered '02 Aug 2020 15:50'	System	02 Aug 2020 19:50:17
	System	02 Aug 2020 19:50:17

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 7'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:15', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7e8cb39f-4128-40e8-bd5f-99b1243ea49f' User entered 'None (1)'	System	03 Aug 2020 16:09:26
	System	03 Aug 2020 16:09:26

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:17', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7e8cb39f-4128-40e8-bd5f-99b1243ea49f' User entered 'No (N)'	System	03 Aug 2020 16:09:26
	System	03 Aug 2020 16:09:26

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:20', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7e8cb39f-4128-40e8-bd5f-99b1243ea49f' User entered 'No (N)'	System	03 Aug 2020 16:09:26
	System	03 Aug 2020 16:09:26

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7e8cb39f-4128-40e8-bd5f-99b1243ea49f' User entered 'None (1)'	System	03 Aug 2020 16:09:26
	System	03 Aug 2020 16:09:26

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:24', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7e8cb39f-4128-40e8-bd5f-99b1243ea49f' User entered '03 Aug 2020 12:09'	System	03 Aug 2020 16:09:26
	System	03 Aug 2020 16:09:26

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 16:11'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 18:41'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T19:56:31', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '3b306357-197c-4bb1-be80-6ceb2798ca47' User entered 'None (0)'	System	29 Jul 2020 00:07:35
	System	29 Jul 2020 00:07:35

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T19:56:41', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '3b306357-197c-4bb1-be80-6ceb2798ca47' User entered 'None (0)'	System	29 Jul 2020 00:07:35
	System	29 Jul 2020 00:07:35

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T19:56:48', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '3b306357-197c-4bb1-be80-6ceb2798ca47' User entered 'None (0)'	System	29 Jul 2020 00:07:35
	System	29 Jul 2020 00:07:35

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T19:56:53', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '3b306357-197c-4bb1-be80-6ceb2798ca47' User entered 'None (0)'	System	29 Jul 2020 00:07:35
	System	29 Jul 2020 00:07:35

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T19:56:56', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '3b306357-197c-4bb1-be80-6ceb2798ca47' User entered 'None (0)'	System	29 Jul 2020 00:07:35
	System	29 Jul 2020 00:07:35

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T19:57:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '3b306357-197c-4bb1-be80-6ceb2798ca47' User entered 'None (0)'	System	29 Jul 2020 00:07:35
	System	29 Jul 2020 00:07:35

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:07:25', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '3b306357-197c-4bb1-be80-6ceb2798ca47' User entered 'No (N)'	System	29 Jul 2020 00:07:35
	System	29 Jul 2020 00:07:35

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-28T20:07:31', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '3b306357-197c-4bb1-be80-6ceb2798ca47' User entered '28 Jul 2020 20:07'	System	29 Jul 2020 00:07:35
	System	29 Jul 2020 00:07:35

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Jul 2020 19:36'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 2'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:00:50', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5421b08b-884d-49af-ae36-4b9f56895977'	System	29 Jul 2020 17:01:40
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:01:40

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:01:01', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5421b08b-884d-49af-ae36-4b9f56895977'	System	29 Jul 2020 17:01:40
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:01:40

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:01:06', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5421b08b-884d-49af-ae36-4b9f56895977'	System	29 Jul 2020 17:01:40
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:01:40

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:01:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5421b08b-884d-49af-ae36-4b9f56895977' User entered 'None (0)'	System	29 Jul 2020 17:01:40
	System	29 Jul 2020 17:01:40

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:01:23', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5421b08b-884d-49af-ae36-4b9f56895977'	System	29 Jul 2020 17:01:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	29 Jul 2020 17:01:40

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:01:27', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5421b08b-884d-49af-ae36-4b9f56895977'	System	29 Jul 2020 17:01:40
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:01:40

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:01:32', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5421b08b-884d-49af-ae36-4b9f56895977' User entered 'No (N)'	System	29 Jul 2020 17:01:40
	System	29 Jul 2020 17:01:40

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-29T13:01:36', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5421b08b-884d-49af-ae36-4b9f56895977' User entered '29 Jul 2020 13:01'	System	29 Jul 2020 17:01:40
	System	29 Jul 2020 17:01:40

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 3'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:16', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9321b5fb-44a1-46d1-bb4c-fe1061cf3866' User entered 'None (0)'	System	30 Jul 2020 16:26:43
	System	30 Jul 2020 16:26:43

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9321b5fb-44a1-46d1-bb4c-fe1061cf3866' User entered 'None (0)'	System	30 Jul 2020 16:26:43
	System	30 Jul 2020 16:26:43

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9321b5fb-44a1-46d1-bb4c-fe1061cf3866' User entered 'None (0)'	System	30 Jul 2020 16:26:43
	System	30 Jul 2020 16:26:43

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:24', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9321b5fb-44a1-46d1-bb4c-fe1061cf3866' User entered 'None (0)'	System	30 Jul 2020 16:26:43
	System	30 Jul 2020 16:26:43

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:27', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9321b5fb-44a1-46d1-bb4c-fe1061cf3866' User entered 'None (0)'	System	30 Jul 2020 16:26:43
	System	30 Jul 2020 16:26:43

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:30', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9321b5fb-44a1-46d1-bb4c-fe1061cf3866' User entered 'None (0)'	System	30 Jul 2020 16:26:43
	System	30 Jul 2020 16:26:43

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:33', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9321b5fb-44a1-46d1-bb4c-fe1061cf3866' User entered 'No (N)'	System	30 Jul 2020 16:26:43
	System	30 Jul 2020 16:26:43

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-30T12:26:40', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9321b5fb-44a1-46d1-bb4c-fe1061cf3866' User entered '30 Jul 2020 12:26'	System	30 Jul 2020 16:26:43
	System	30 Jul 2020 16:26:43

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 4'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:23', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '836b1f3f-38a3-4399-b5a7-45380dae9d39' User entered 'None (0)'	System	31 Jul 2020 21:18:45
	System	31 Jul 2020 21:18:45

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:27', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '836b1f3f-38a3-4399-b5a7-45380dae9d39' User entered 'None (0)'	System	31 Jul 2020 21:18:45
	System	31 Jul 2020 21:18:45

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:29', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '836b1f3f-38a3-4399-b5a7-45380dae9d39' User entered 'None (0)'	System	31 Jul 2020 21:18:45
	System	31 Jul 2020 21:18:45

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:32', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '836b1f3f-38a3-4399-b5a7-45380dae9d39' User entered 'None (0)'	System	31 Jul 2020 21:18:45
	System	31 Jul 2020 21:18:45

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '836b1f3f-38a3-4399-b5a7-45380dae9d39' User entered 'None (0)'	System	31 Jul 2020 21:18:45
	System	31 Jul 2020 21:18:45

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:37', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '836b1f3f-38a3-4399-b5a7-45380dae9d39' User entered 'None (0)'	System	31 Jul 2020 21:18:45
	System	31 Jul 2020 21:18:45

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:39', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '836b1f3f-38a3-4399-b5a7-45380dae9d39' User entered 'No (N)'	System	31 Jul 2020 21:18:45
	System	31 Jul 2020 21:18:45

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-07-31T17:18:42', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '836b1f3f-38a3-4399-b5a7-45380dae9d39' User entered '31 Jul 2020 17:18'	System	31 Jul 2020 21:18:45
	System	31 Jul 2020 21:18:45

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 5'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:01:57', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e078eb6-485d-4045-a035-87ebc0a2b2f5' User entered 'None (0)'	System	02 Aug 2020 03:02:20
	System	02 Aug 2020 03:02:20

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:02:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e078eb6-485d-4045-a035-87ebc0a2b2f5' User entered 'None (0)'	System	02 Aug 2020 03:02:20
	System	02 Aug 2020 03:02:20

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:02:03', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e078eb6-485d-4045-a035-87ebc0a2b2f5' User entered 'None (0)'	System	02 Aug 2020 03:02:20
	System	02 Aug 2020 03:02:20

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:02:06', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e078eb6-485d-4045-a035-87ebc0a2b2f5' User entered 'None (0)'	System	02 Aug 2020 03:02:20
	System	02 Aug 2020 03:02:20

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:02:09', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e078eb6-485d-4045-a035-87ebc0a2b2f5' User entered 'None (0)'	System	02 Aug 2020 03:02:20
	System	02 Aug 2020 03:02:20

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:02:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e078eb6-485d-4045-a035-87ebc0a2b2f5' User entered 'None (0)'	System	02 Aug 2020 03:02:20
	System	02 Aug 2020 03:02:20

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:02:16', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e078eb6-485d-4045-a035-87ebc0a2b2f5' User entered 'No (N)'	System	02 Aug 2020 03:02:20
	System	02 Aug 2020 03:02:20

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-01T23:02:18', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e078eb6-485d-4045-a035-87ebc0a2b2f5'	System	02 Aug 2020 03:02:20
User entered '01 Aug 2020 23:02'	System	02 Aug 2020 03:02:20

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 6'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '316fa0bb-68e4-44a6-9bca-0c5e1aada784' User entered 'None (0)'	System	02 Aug 2020 19:50:44
	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:26', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '316fa0bb-68e4-44a6-9bca-0c5e1aada784'	System	02 Aug 2020 19:50:44
User entered 'No interference with activity (1)'	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:29', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '316fa0bb-68e4-44a6-9bca-0c5e1aada784' User entered 'None (0)'	System	02 Aug 2020 19:50:44
	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:31', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '316fa0bb-68e4-44a6-9bca-0c5e1aada784' User entered 'None (0)'	System	02 Aug 2020 19:50:44
	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '316fa0bb-68e4-44a6-9bca-0c5e1aada784' User entered 'None (0)'	System	02 Aug 2020 19:50:44
	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:38', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '316fa0bb-68e4-44a6-9bca-0c5e1aada784' User entered 'None (0)'	System	02 Aug 2020 19:50:44
	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:41', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '316fa0bb-68e4-44a6-9bca-0c5e1aada784' User entered 'No (N)'	System	02 Aug 2020 19:50:44
	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-02T15:50:42', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '316fa0bb-68e4-44a6-9bca-0c5e1aada784' User entered '02 Aug 2020 15:50'	System	02 Aug 2020 19:50:44
	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 7'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:27', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fbf32b1b-8012-4d24-9e79-16bf4c16b130' User entered 'None (0)'	System	03 Aug 2020 16:09:49
	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:30', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fbf32b1b-8012-4d24-9e79-16bf4c16b130'	System	03 Aug 2020 16:09:49
User entered 'No interference with activity (1)'	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:32', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fbf32b1b-8012-4d24-9e79-16bf4c16b130' User entered 'None (0)'	System	03 Aug 2020 16:09:49
	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:34', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fbf32b1b-8012-4d24-9e79-16bf4c16b130' User entered 'None (0)'	System	03 Aug 2020 16:09:49
	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:37', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fbf32b1b-8012-4d24-9e79-16bf4c16b130' User entered 'None (0)'	System	03 Aug 2020 16:09:49
	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:39', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fbf32b1b-8012-4d24-9e79-16bf4c16b130' User entered 'None (0)'	System	03 Aug 2020 16:09:49
	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:41', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fbf32b1b-8012-4d24-9e79-16bf4c16b130' User entered 'No (N)'	System	03 Aug 2020 16:09:49
	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-03T12:09:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'fbf32b1b-8012-4d24-9e79-16bf4c16b130' User entered '03 Aug 2020 12:09'	System	03 Aug 2020 16:09:49
	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	02 Aug 2020 19:50:44
User entered 'Day 8'	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:21:06

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-04T12:00:33', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c1fa5153-718d-4268-837b-2c373a20aa85'	System	04 Aug 2020 16:00:39
User entered 'Some interference with activity (2)'	System	04 Aug 2020 16:00:39

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-04T12:00:38', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c1fa5153-718d-4268-837b-2c373a20aa85'	System	04 Aug 2020 16:00:39
User entered '04 Aug 2020 12:00'	System	04 Aug 2020 16:00:39

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	03 Aug 2020 16:09:49
User entered 'Day 9'	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:21:06

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-05T13:18:11', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2f64de2d-2a5e-41ab-a944-8fe7967a8b25'	System	05 Aug 2020 17:18:17
User entered 'No interference with activity (1)'	System	05 Aug 2020 17:18:17

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-05T13:18:14', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2f64de2d-2a5e-41ab-a944-8fe7967a8b25'	System	05 Aug 2020 17:18:17
User entered '05 Aug 2020 13:18'	System	05 Aug 2020 17:18:17

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	04 Aug 2020 16:00:39
User entered 'Day 10'	System	04 Aug 2020 16:00:39

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:21:06

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-07T00:02:34', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '67b6a07f-2f9c-4cc9-99b1-66b662513dcc' User entered 'None (0)'	System	07 Aug 2020 04:02:39
	System	07 Aug 2020 04:02:39

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-07T00:02:37', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '67b6a07f-2f9c-4cc9-99b1-66b662513dcc' User entered '07 Aug 2020 00:02'	System	07 Aug 2020 04:02:39
	System	07 Aug 2020 04:02:39

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 16:00:39

US3122083

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 16:00:39

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	02 Aug 2020 19:50:44
User entered 'Day 8'	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-04T12:00:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'bef2581f-408b-4e93-871f-c93f18f2c3a4'	System	04 Aug 2020 16:00:48
User entered 'No (N)'	System	04 Aug 2020 16:00:48

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-04T12:00:46', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'bef2581f-408b-4e93-871f-c93f18f2c3a4'	System	04 Aug 2020 16:00:48
User entered '04 Aug 2020 12:00'	System	04 Aug 2020 16:00:48

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 19:50:44

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	03 Aug 2020 16:09:49
User entered 'Day 9'	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-05T13:18:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'bcde4841-3135-4a77-8dd1-1c6787021061'	System	05 Aug 2020 17:18:23
User entered 'No (N)'	System	05 Aug 2020 17:18:23

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-05T13:18:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'bcde4841-3135-4a77-8dd1-1c6787021061'	System	05 Aug 2020 17:18:23
User entered '05 Aug 2020 13:18'	System	05 Aug 2020 17:18:23

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 16:09:49

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	04 Aug 2020 16:00:39
User entered 'Day 10'	System	04 Aug 2020 16:00:39

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-07T00:02:41', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9e2a9341-adc8-4c33-b283-03bfddd02937' User entered 'No (N)'	System	07 Aug 2020 04:02:48
	System	07 Aug 2020 04:02:48

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-07T00:02:44', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9e2a9341-adc8-4c33-b283-03bfddd02937' User entered '07 Aug 2020 00:02'	System	07 Aug 2020 04:02:48
	System	07 Aug 2020 04:02:48

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 16:00:39

US3122083

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 16:00:39

US3122083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 23:01:27

US3122083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '06 Aug 2020'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 23:01:27

US3122083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	07 Aug 2020 23:01:27

US3122083

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Leah Corts (b) (4)	07 Aug 2020 23:01:27

US3122083

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	10 Aug 2020 14:30:18

US3122083

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	10 Aug 2020 14:30:18

US3122083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:56:08

US3122083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12 Aug 2020'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	19 Aug 2020 16:56:08

US3122083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Aubrey Farray (b) (4)	19 Aug 2020 16:56:08

US3122083

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Aubrey Farrey (b) (4) (b) (4)	19 Aug 2020 16:56:08

US3122083

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	19 Aug 2020 16:56:11

US3122083

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	19 Aug 2020 16:56:11

US3122083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farrah (b) (4)	19 Aug 2020 16:56:28

US3122083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '19 Aug 2020'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:56:28

US3122083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Aubrey Farrah (b) (4)	19 Aug 2020 16:56:28

US3122083

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Aubrey Farrey (b) (4)	19 Aug 2020 16:56:28

US3122083

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:56:34

US3122083

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	19 Aug 2020 16:56:34

US3122083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:54:21

US3122083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:54:21

US3122083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Clinic (Clinic)'	Aubrey Farray (b) (4)	26 Aug 2020 19:54:21

US3122083

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'VISIT2'	System	26 Aug 2020 19:54:21

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User accepted default value 'Pre-Dose (PREDOSE)'	Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '13:20'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '26 Aug 2020 13:20'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '98.3' F	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (Oral)'	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Aubrey Farray (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '73'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'bpm'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '14'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'breaths/min'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '118'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'mmHg'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '79'	(b) (4) Aubrey Farrah (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'mmHg'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User accepted default value 'Post-Dose (POSTDOSE)'	Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '26 Aug 2020'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '15:20'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '98.3' F	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (Oral)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '59'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'bpm'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '16'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'breaths/min'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '120'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'mmHg'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '81'	(b) (4) Aubrey Farrey (b) (4) (b) (4)	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'mmHg'	System	26 Aug 2020 19:59:39

US3122083

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Aubrey Farray (b) (4)	31 Aug 2020 18:39:41
User entered 'Yes (Y)'	(b) (4)	
	Aubrey Farray (b) (4)	26 Aug 2020 19:59:47
	(b) (4)	

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '14:43'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '26 Aug 2020 14:43'	System	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'ONCE'	System	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 18:47:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farrah (b) (4)	26 Aug 2020 20:00:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '26 Aug 2020'	(b) (4) Aubrey Farrey (b) (4)	26 Aug 2020 20:00:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '14:14'	(b) (4) Aubrey Farrah (b) (4)	26 Aug 2020 20:00:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '26 Aug 2020 14:14'	System	26 Aug 2020 20:00:08

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '26 Aug 2020'	(b) (4) Aubrey Farray (b) (4)	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Aubrey Farray (b) (4) (b) (4)	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4)	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '14:21'	(b) (4) Aubrey Farray (b) (4) (b) (4)	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '26 Aug 2020 14:21'	System	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Aubrey Farray (b) (4) (b) (4)	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Aubrey Farray (b) (4)	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Aubrey Farray (b) (4)	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered empty.	System	31 Aug 2020 18:38:19

US3122083

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	26 Aug 2020 20:00:13

US3122083

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	26 Aug 2020 20:00:13

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:11:51', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '562f172c-e834-4e82-ab94-4c114d6f8272' User entered 'Yes (Y)'	System	26 Aug 2020 19:12:07
	System	26 Aug 2020 19:12:07

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:11:56', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '562f172c-e834-4e82-ab94-4c114d6f8272' User entered '98.3'	System	26 Aug 2020 19:12:07
	System	26 Aug 2020 19:12:07

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:11:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '562f172c-e834-4e82-ab94-4c114d6f8272' User entered 'No (N)'	System	26 Aug 2020 19:12:07
	System	26 Aug 2020 19:12:07

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:12:03', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '562f172c-e834-4e82-ab94-4c114d6f8272' User entered '26 Aug 2020 15:12'	System	26 Aug 2020 19:12:07
	System	26 Aug 2020 19:12:07

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 15:03'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 17:33'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:48:25', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5296a4d7-efe1-4a1d-9a55-bda23c8f2851' User entered 'Yes (Y)'	System	27 Aug 2020 12:49:59
	System	27 Aug 2020 12:49:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:49:51', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5296a4d7-efe1-4a1d-9a55-bda23c8f2851' User entered '97.5'	System	27 Aug 2020 12:49:59
	System	27 Aug 2020 12:49:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:49:54', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5296a4d7-efe1-4a1d-9a55-bda23c8f2851'	System	27 Aug 2020 12:49:59
User entered 'No (N)'	System	27 Aug 2020 12:49:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:49:57', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5296a4d7-efe1-4a1d-9a55-bda23c8f2851' User entered '27 Aug 2020 08:49'	System	27 Aug 2020 12:49:59
	System	27 Aug 2020 12:49:59

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 18:28'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 2'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:07', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0b3cfc7e-7968-4055-86fd-6e8f5580f86a' User entered 'Yes (Y)'	System	27 Aug 2020 16:03:42
	System	27 Aug 2020 16:03:42

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:14', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0b3cfc7e-7968-4055-86fd-6e8f5580f86a' User entered '97.5'	System	27 Aug 2020 16:03:42
	System	27 Aug 2020 16:03:42

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:16', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0b3cfc7e-7968-4055-86fd-6e8f5580f86a' User entered 'No (N)'	System	27 Aug 2020 16:03:42
	System	27 Aug 2020 16:03:42

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0b3cfc7e-7968-4055-86fd-6e8f5580f86a' User entered '27 Aug 2020 12:03'	System	27 Aug 2020 16:03:42
	System	27 Aug 2020 16:03:42

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 3'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:30:05', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'cc4b46a0-093e-4aea-a6f9-ec1f65e082a9' User entered 'Yes (Y)'	System	28 Aug 2020 16:30:17
	System	28 Aug 2020 16:30:17

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:30:09', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'cc4b46a0-093e-4aea-a6f9-ec1f65e082a9' User entered '97.1'	System	28 Aug 2020 16:30:17
	System	28 Aug 2020 16:30:17

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:30:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'cc4b46a0-093e-4aea-a6f9-ec1f65e082a9'	System	28 Aug 2020 16:30:17
User entered 'No (N)'	System	28 Aug 2020 16:30:17

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:30:14', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'cc4b46a0-093e-4aea-a6f9-ec1f65e082a9' User entered '28 Aug 2020 12:30'	System	28 Aug 2020 16:30:17
	System	28 Aug 2020 16:30:17

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 4'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:56:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5d9eeeee-8943-4aee-a3dc-a989a1337c46' User entered 'Yes (Y)'	System	29 Aug 2020 16:56:54
	System	29 Aug 2020 16:56:54

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:56:46', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5d9eeeee-8943-4aee-a3dc-a989a1337c46' User entered '97.8'	System	29 Aug 2020 16:56:54
	System	29 Aug 2020 16:56:54

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:56:50', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5d9eeeee-8943-4aee-a3dc-a989a1337c46'	System	29 Aug 2020 16:56:54
User entered 'No (N)'	System	29 Aug 2020 16:56:54

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:56:52', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '5d9eeeee-8943-4aee-a3dc-a989a1337c46' User entered '29 Aug 2020 12:56'	System	29 Aug 2020 16:56:54
	System	29 Aug 2020 16:56:54

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 5'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:27:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8f3e1f83-0d89-4744-b1d5-84203eb25390' User entered 'Yes (Y)'	System	30 Aug 2020 18:27:39
	System	30 Aug 2020 18:27:39

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:27:26', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8f3e1f83-0d89-4744-b1d5-84203eb25390' User entered '97.7'	System	30 Aug 2020 18:27:39
	System	30 Aug 2020 18:27:39

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:27:28', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8f3e1f83-0d89-4744-b1d5-84203eb25390'	System	30 Aug 2020 18:27:39
User entered 'No (N)'	System	30 Aug 2020 18:27:39

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:27:36', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8f3e1f83-0d89-4744-b1d5-84203eb25390' User entered '30 Aug 2020 14:27'	System	30 Aug 2020 18:27:39
	System	30 Aug 2020 18:27:39

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 6'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:14:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a4fb46be-9fc4-4e9b-a8e9-cb401c115db3' User entered 'Yes (Y)'	System	31 Aug 2020 16:25:00
	System	31 Aug 2020 16:25:00

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:15:46', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a4fb46be-9fc4-4e9b-a8e9-cb401c115db3' User entered '97.6'	System	31 Aug 2020 16:25:00
	System	31 Aug 2020 16:25:00

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:15:48', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a4fb46be-9fc4-4e9b-a8e9-cb401c115db3'	System	31 Aug 2020 16:25:00
User entered 'No (N)'	System	31 Aug 2020 16:25:00

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:15:51', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a4fb46be-9fc4-4e9b-a8e9-cb401c115db3'	System	31 Aug 2020 16:25:00
User entered '31 Aug 2020 12:15'	System	31 Aug 2020 16:25:00

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 7'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e2c89913-d545-4fe7-b3ed-454e7a68e8db' User entered 'Yes (Y)'	System	01 Sep 2020 16:42:35
	System	01 Sep 2020 16:42:35

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:27', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e2c89913-d545-4fe7-b3ed-454e7a68e8db' User entered '97.7'	System	01 Sep 2020 16:42:35
	System	01 Sep 2020 16:42:35

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:29', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e2c89913-d545-4fe7-b3ed-454e7a68e8db' User entered 'No (N)'	System	01 Sep 2020 16:42:35
	System	01 Sep 2020 16:42:35

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:32', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e2c89913-d545-4fe7-b3ed-454e7a68e8db' User entered '01 Sep 2020 12:42'	System	01 Sep 2020 16:42:35
	System	01 Sep 2020 16:42:35

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:09:32', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '60148345-6719-4adb-ab73-05c4259b1094'	System	26 Aug 2020 19:10:30
User entered 'None (1)'	System	26 Aug 2020 19:10:30

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:09:37', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '60148345-6719-4adb-ab73-05c4259b1094'	System	26 Aug 2020 19:10:30
User entered 'No (N)'	System	26 Aug 2020 19:10:30

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:09:42', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '60148345-6719-4adb-ab73-05c4259b1094'	System	26 Aug 2020 19:10:30
User entered 'No (N)'	System	26 Aug 2020 19:10:30

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:09:47', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '60148345-6719-4adb-ab73-05c4259b1094'	System	26 Aug 2020 19:10:30
User entered 'None (1)'	System	26 Aug 2020 19:10:30

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:09:52', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '60148345-6719-4adb-ab73-05c4259b1094'	System	26 Aug 2020 19:10:30
User entered '26 Aug 2020 15:09'	System	26 Aug 2020 19:10:30

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 15:03'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 17:33'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:05', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '863c3622-250b-4513-bbbd-502b69d191e1' User entered 'None (1)'	System	27 Aug 2020 12:50:26
	System	27 Aug 2020 12:50:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:10', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '863c3622-250b-4513-bbbd-502b69d191e1' User entered 'No (N)'	System	27 Aug 2020 12:50:26
	System	27 Aug 2020 12:50:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:13', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '863c3622-250b-4513-bbbd-502b69d191e1'	System	27 Aug 2020 12:50:26
User entered 'No (N)'	System	27 Aug 2020 12:50:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:20', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '863c3622-250b-4513-bbbd-502b69d191e1' User entered 'None (1)'	System	27 Aug 2020 12:50:26
	System	27 Aug 2020 12:50:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:23', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '863c3622-250b-4513-bbbd-502b69d191e1' User entered '27 Aug 2020 08:50'	System	27 Aug 2020 12:50:26
	System	27 Aug 2020 12:50:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 18:28'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 2'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dfbc3cae-2576-4873-92bc-ae8b79e5c858'	System	27 Aug 2020 16:03:50
User entered 'None (1)'	System	27 Aug 2020 16:03:50

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:24', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dfbc3cae-2576-4873-92bc-ae8b79e5c858'	System	27 Aug 2020 16:03:50
User entered 'No (N)'	System	27 Aug 2020 16:03:50

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:26', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dfbc3cae-2576-4873-92bc-ae8b79e5c858'	System	27 Aug 2020 16:03:50
User entered 'No (N)'	System	27 Aug 2020 16:03:50

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:28', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dfbc3cae-2576-4873-92bc-ae8b79e5c858'	System	27 Aug 2020 16:03:50
User entered 'None (1)'	System	27 Aug 2020 16:03:50

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:31', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'dfbc3cae-2576-4873-92bc-ae8b79e5c858' User entered '27 Aug 2020 12:03'	System	27 Aug 2020 16:03:50
	System	27 Aug 2020 16:03:50

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 3'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:17', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ceb9bdb6-0cc9-41f6-babb-1a9ea8a0e334' User entered 'None (1)'	System	28 Aug 2020 16:13:26
	System	28 Aug 2020 16:13:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ceb9bdb6-0cc9-41f6-babb-1a9ea8a0e334'	System	28 Aug 2020 16:13:26
User entered 'No (N)'	System	28 Aug 2020 16:13:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:20', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ceb9bdb6-0cc9-41f6-babb-1a9ea8a0e334' User entered 'No (N)'	System	28 Aug 2020 16:13:26
	System	28 Aug 2020 16:13:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ceb9bdb6-0cc9-41f6-babb-1a9ea8a0e334' User entered 'None (1)'	System	28 Aug 2020 16:13:26
	System	28 Aug 2020 16:13:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:24', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ceb9bdb6-0cc9-41f6-babb-1a9ea8a0e334' User entered '28 Aug 2020 12:13'	System	28 Aug 2020 16:13:26
	System	28 Aug 2020 16:13:26

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 4'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:56:55', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '1153d856-7b4f-47bd-9654-3b80cd264d41'	System	29 Aug 2020 16:57:05
User entered 'None (1)'	System	29 Aug 2020 16:57:05

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:56:57', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '1153d856-7b4f-47bd-9654-3b80cd264d41'	System	29 Aug 2020 16:57:05
User entered 'No (N)'	System	29 Aug 2020 16:57:05

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:56:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '1153d856-7b4f-47bd-9654-3b80cd264d41'	System	29 Aug 2020 16:57:05
User entered 'No (N)'	System	29 Aug 2020 16:57:05

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:01', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '1153d856-7b4f-47bd-9654-3b80cd264d41'	System	29 Aug 2020 16:57:05
User entered 'None (1)'	System	29 Aug 2020 16:57:05

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:03', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '1153d856-7b4f-47bd-9654-3b80cd264d41' User entered '29 Aug 2020 12:57'	System	29 Aug 2020 16:57:05
	System	29 Aug 2020 16:57:05

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 5'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:07', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9b21f48a-e267-4342-ac2e-2765bd789e8c' User entered 'None (1)'	System	30 Aug 2020 18:28:25
	System	30 Aug 2020 18:28:25

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9b21f48a-e267-4342-ac2e-2765bd789e8c' User entered 'No (N)'	System	30 Aug 2020 18:28:25
	System	30 Aug 2020 18:28:25

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:14', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9b21f48a-e267-4342-ac2e-2765bd789e8c' User entered 'No (N)'	System	30 Aug 2020 18:28:25
	System	30 Aug 2020 18:28:25

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:18', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9b21f48a-e267-4342-ac2e-2765bd789e8c' User entered 'None (1)'	System	30 Aug 2020 18:28:25
	System	30 Aug 2020 18:28:25

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:21', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9b21f48a-e267-4342-ac2e-2765bd789e8c' User entered '30 Aug 2020 14:28'	System	30 Aug 2020 18:28:25
	System	30 Aug 2020 18:28:25

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 6'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:15:57', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c8887cfa-d792-4321-818d-a53a7234305a' User entered 'None (1)'	System	31 Aug 2020 16:25:12
	System	31 Aug 2020 16:25:12

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:15:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c8887cfa-d792-4321-818d-a53a7234305a' User entered 'No (N)'	System	31 Aug 2020 16:25:12
	System	31 Aug 2020 16:25:12

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:02', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c8887cfa-d792-4321-818d-a53a7234305a' User entered 'No (N)'	System	31 Aug 2020 16:25:12
	System	31 Aug 2020 16:25:12

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:04', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c8887cfa-d792-4321-818d-a53a7234305a' User entered 'None (1)'	System	31 Aug 2020 16:25:12
	System	31 Aug 2020 16:25:12

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:06', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c8887cfa-d792-4321-818d-a53a7234305a' User entered '31 Aug 2020 12:16'	System	31 Aug 2020 16:25:12
	System	31 Aug 2020 16:25:12

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 7'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:04', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e1bf6e42-5103-4e8c-8cc8-2dc29a141636'	System	01 Sep 2020 16:42:14
User entered 'None (1)'	System	01 Sep 2020 16:42:14

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:07', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e1bf6e42-5103-4e8c-8cc8-2dc29a141636' User entered 'No (N)'	System	01 Sep 2020 16:42:14
	System	01 Sep 2020 16:42:14

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:08', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e1bf6e42-5103-4e8c-8cc8-2dc29a141636' User entered 'No (N)'	System	01 Sep 2020 16:42:14
	System	01 Sep 2020 16:42:14

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:10', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e1bf6e42-5103-4e8c-8cc8-2dc29a141636'	System	01 Sep 2020 16:42:14
User entered 'None (1)'	System	01 Sep 2020 16:42:14

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e1bf6e42-5103-4e8c-8cc8-2dc29a141636'	System	01 Sep 2020 16:42:14
User entered '01 Sep 2020 12:42'	System	01 Sep 2020 16:42:14

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:09:56', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f4d23ef4-06ef-4989-8964-f3a4f7bd820c' User entered 'None (0)'	System	26 Aug 2020 19:10:37
	System	26 Aug 2020 19:10:37

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:09:58', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f4d23ef4-06ef-4989-8964-f3a4f7bd820c' User entered 'None (0)'	System	26 Aug 2020 19:10:37
	System	26 Aug 2020 19:10:37

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:10:01', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f4d23ef4-06ef-4989-8964-f3a4f7bd820c' User entered 'None (0)'	System	26 Aug 2020 19:10:37
	System	26 Aug 2020 19:10:37

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:10:03', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f4d23ef4-06ef-4989-8964-f3a4f7bd820c' User entered 'None (0)'	System	26 Aug 2020 19:10:37
	System	26 Aug 2020 19:10:37

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:10:06', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f4d23ef4-06ef-4989-8964-f3a4f7bd820c' User entered 'None (0)'	System	26 Aug 2020 19:10:37
	System	26 Aug 2020 19:10:37

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:10:08', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f4d23ef4-06ef-4989-8964-f3a4f7bd820c' User entered 'None (0)'	System	26 Aug 2020 19:10:37
	System	26 Aug 2020 19:10:37

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:10:10', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f4d23ef4-06ef-4989-8964-f3a4f7bd820c' User entered 'No (N)'	System	26 Aug 2020 19:10:37
	System	26 Aug 2020 19:10:37

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-26T15:10:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'f4d23ef4-06ef-4989-8964-f3a4f7bd820c' User entered '26 Aug 2020 15:10'	System	26 Aug 2020 19:10:37
	System	26 Aug 2020 19:10:37

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 15:03'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 17:33'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:27', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ff16b9d0-4c73-4045-a849-026fede35f27' User entered 'None (0)'	System	27 Aug 2020 12:50:48
	System	27 Aug 2020 12:50:48

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:29', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ff16b9d0-4c73-4045-a849-026fede35f27' User entered 'None (0)'	System	27 Aug 2020 12:50:48
	System	27 Aug 2020 12:50:48

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:32', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ff16b9d0-4c73-4045-a849-026fede35f27' User entered 'None (0)'	System	27 Aug 2020 12:50:48
	System	27 Aug 2020 12:50:48

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ff16b9d0-4c73-4045-a849-026fede35f27' User entered 'None (0)'	System	27 Aug 2020 12:50:48
	System	27 Aug 2020 12:50:48

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:37', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ff16b9d0-4c73-4045-a849-026fede35f27' User entered 'None (0)'	System	27 Aug 2020 12:50:48
	System	27 Aug 2020 12:50:48

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:39', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ff16b9d0-4c73-4045-a849-026fede35f27' User entered 'None (0)'	System	27 Aug 2020 12:50:48
	System	27 Aug 2020 12:50:48

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:42', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ff16b9d0-4c73-4045-a849-026fede35f27'	System	27 Aug 2020 12:50:48
User entered 'No (N)'	System	27 Aug 2020 12:50:48

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T08:50:45', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'ff16b9d0-4c73-4045-a849-026fede35f27'	System	27 Aug 2020 12:50:48
User entered '27 Aug 2020 08:50'	System	27 Aug 2020 12:50:48

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '26 Aug 2020 18:28'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 2'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:34', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2b63ec5f-9c6b-4b85-ae0b-6b0fb582ef76'	System	27 Aug 2020 16:04:02
User entered 'None (0)'	System	27 Aug 2020 16:04:02

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2b63ec5f-9c6b-4b85-ae0b-6b0fb582ef76'	System	27 Aug 2020 16:04:02
User entered 'None (0)'	System	27 Aug 2020 16:04:02

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:37', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2b63ec5f-9c6b-4b85-ae0b-6b0fb582ef76'	System	27 Aug 2020 16:04:02
User entered 'None (0)'	System	27 Aug 2020 16:04:02

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:38', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2b63ec5f-9c6b-4b85-ae0b-6b0fb582ef76' User entered 'None (0)'	System	27 Aug 2020 16:04:02
	System	27 Aug 2020 16:04:02

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:40', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2b63ec5f-9c6b-4b85-ae0b-6b0fb582ef76'	System	27 Aug 2020 16:04:02
User entered 'None (0)'	System	27 Aug 2020 16:04:02

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:42', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2b63ec5f-9c6b-4b85-ae0b-6b0fb582ef76' User entered 'None (0)'	System	27 Aug 2020 16:04:02
	System	27 Aug 2020 16:04:02

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:44', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2b63ec5f-9c6b-4b85-ae0b-6b0fb582ef76'	System	27 Aug 2020 16:04:02
User entered 'No (N)'	System	27 Aug 2020 16:04:02

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-27T12:03:45', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2b63ec5f-9c6b-4b85-ae0b-6b0fb582ef76'	System	27 Aug 2020 16:04:02
User entered '27 Aug 2020 12:03'	System	27 Aug 2020 16:04:02

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 3'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:12:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '373f5014-8642-47d6-a61d-ce03293911b7' User entered 'None (0)'	System	28 Aug 2020 16:13:14
	System	28 Aug 2020 16:13:14

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '373f5014-8642-47d6-a61d-ce03293911b7' User entered 'None (0)'	System	28 Aug 2020 16:13:14
	System	28 Aug 2020 16:13:14

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:02', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '373f5014-8642-47d6-a61d-ce03293911b7' User entered 'None (0)'	System	28 Aug 2020 16:13:14
	System	28 Aug 2020 16:13:14

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:04', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '373f5014-8642-47d6-a61d-ce03293911b7' User entered 'None (0)'	System	28 Aug 2020 16:13:14
	System	28 Aug 2020 16:13:14

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:05', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '373f5014-8642-47d6-a61d-ce03293911b7' User entered 'None (0)'	System	28 Aug 2020 16:13:14
	System	28 Aug 2020 16:13:14

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:07', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '373f5014-8642-47d6-a61d-ce03293911b7' User entered 'None (0)'	System	28 Aug 2020 16:13:14
	System	28 Aug 2020 16:13:14

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:09', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '373f5014-8642-47d6-a61d-ce03293911b7' User entered 'No (N)'	System	28 Aug 2020 16:13:14
	System	28 Aug 2020 16:13:14

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-28T12:13:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '373f5014-8642-47d6-a61d-ce03293911b7' User entered '28 Aug 2020 12:13'	System	28 Aug 2020 16:13:14
	System	28 Aug 2020 16:13:14

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 4'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:07', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '95910b8a-9ec4-491e-8b19-0c85f63290e8' User entered 'None (0)'	System	29 Aug 2020 16:57:24
	System	29 Aug 2020 16:57:24

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:08', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '95910b8a-9ec4-491e-8b19-0c85f63290e8' User entered 'None (0)'	System	29 Aug 2020 16:57:24
	System	29 Aug 2020 16:57:24

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:10', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '95910b8a-9ec4-491e-8b19-0c85f63290e8' User entered 'None (0)'	System	29 Aug 2020 16:57:24
	System	29 Aug 2020 16:57:24

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:12', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '95910b8a-9ec4-491e-8b19-0c85f63290e8' User entered 'None (0)'	System	29 Aug 2020 16:57:24
	System	29 Aug 2020 16:57:24

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:14', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '95910b8a-9ec4-491e-8b19-0c85f63290e8' User entered 'None (0)'	System	29 Aug 2020 16:57:24
	System	29 Aug 2020 16:57:24

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:16', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '95910b8a-9ec4-491e-8b19-0c85f63290e8' User entered 'None (0)'	System	29 Aug 2020 16:57:24
	System	29 Aug 2020 16:57:24

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:18', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '95910b8a-9ec4-491e-8b19-0c85f63290e8' User entered 'No (N)'	System	29 Aug 2020 16:57:24
	System	29 Aug 2020 16:57:24

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-29T12:57:20', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '95910b8a-9ec4-491e-8b19-0c85f63290e8' User entered '29 Aug 2020 12:57'	System	29 Aug 2020 16:57:24
	System	29 Aug 2020 16:57:24

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 5'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:25', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c0d4a264-c43d-4fd6-ac49-0d4906ba1ea4' User entered 'None (0)'	System	30 Aug 2020 18:28:46
	System	30 Aug 2020 18:28:46

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:27', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c0d4a264-c43d-4fd6-ac49-0d4906ba1ea4' User entered 'None (0)'	System	30 Aug 2020 18:28:46
	System	30 Aug 2020 18:28:46

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:30', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c0d4a264-c43d-4fd6-ac49-0d4906ba1ea4' User entered 'None (0)'	System	30 Aug 2020 18:28:46
	System	30 Aug 2020 18:28:46

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:33', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c0d4a264-c43d-4fd6-ac49-0d4906ba1ea4' User entered 'None (0)'	System	30 Aug 2020 18:28:46
	System	30 Aug 2020 18:28:46

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:36', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c0d4a264-c43d-4fd6-ac49-0d4906ba1ea4' User entered 'None (0)'	System	30 Aug 2020 18:28:46
	System	30 Aug 2020 18:28:46

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:38', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c0d4a264-c43d-4fd6-ac49-0d4906ba1ea4' User entered 'None (0)'	System	30 Aug 2020 18:28:46
	System	30 Aug 2020 18:28:46

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:41', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c0d4a264-c43d-4fd6-ac49-0d4906ba1ea4' User entered 'No (N)'	System	30 Aug 2020 18:28:46
	System	30 Aug 2020 18:28:46

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-30T14:28:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'c0d4a264-c43d-4fd6-ac49-0d4906ba1ea4' User entered '30 Aug 2020 14:28'	System	30 Aug 2020 18:28:46
	System	30 Aug 2020 18:28:46

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 6'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:10', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7f94d0c0-1e1b-4621-9846-f421f0bdaf02'	System	31 Aug 2020 16:25:19
User entered 'None (0)'	System	31 Aug 2020 16:25:19

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:13', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7f94d0c0-1e1b-4621-9846-f421f0bdaf02'	System	31 Aug 2020 16:25:19
User entered 'None (0)'	System	31 Aug 2020 16:25:19

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:14', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7f94d0c0-1e1b-4621-9846-f421f0bdaf02'	System	31 Aug 2020 16:25:19
User entered 'None (0)'	System	31 Aug 2020 16:25:19

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:16', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7f94d0c0-1e1b-4621-9846-f421f0bdaf02'	System	31 Aug 2020 16:25:19
User entered 'None (0)'	System	31 Aug 2020 16:25:19

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:18', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7f94d0c0-1e1b-4621-9846-f421f0bdaf02'	System	31 Aug 2020 16:25:19
User entered 'None (0)'	System	31 Aug 2020 16:25:19

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:20', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7f94d0c0-1e1b-4621-9846-f421f0bdaf02'	System	31 Aug 2020 16:25:19
User entered 'None (0)'	System	31 Aug 2020 16:25:19

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7f94d0c0-1e1b-4621-9846-f421f0bdaf02'	System	31 Aug 2020 16:25:19
User entered 'No (N)'	System	31 Aug 2020 16:25:19

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-08-31T12:16:24', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '7f94d0c0-1e1b-4621-9846-f421f0bdaf02'	System	31 Aug 2020 16:25:19
User entered '31 Aug 2020 12:16'	System	31 Aug 2020 16:25:19

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	26 Aug 2020 18:47:08
User entered 'Day 7'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:41:49', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8405f847-b84e-4a60-8a5d-003e86c537f3' User entered 'None (0)'	System	01 Sep 2020 16:42:04
	System	01 Sep 2020 16:42:04

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:41:50', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8405f847-b84e-4a60-8a5d-003e86c537f3' User entered 'None (0)'	System	01 Sep 2020 16:42:04
	System	01 Sep 2020 16:42:04

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:41:52', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8405f847-b84e-4a60-8a5d-003e86c537f3' User entered 'None (0)'	System	01 Sep 2020 16:42:04
	System	01 Sep 2020 16:42:04

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:41:54', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8405f847-b84e-4a60-8a5d-003e86c537f3' User entered 'None (0)'	System	01 Sep 2020 16:42:04
	System	01 Sep 2020 16:42:04

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:41:55', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8405f847-b84e-4a60-8a5d-003e86c537f3' User entered 'None (0)'	System	01 Sep 2020 16:42:04
	System	01 Sep 2020 16:42:04

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:41:57', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8405f847-b84e-4a60-8a5d-003e86c537f3' User entered 'None (0)'	System	01 Sep 2020 16:42:04
	System	01 Sep 2020 16:42:04

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:41:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8405f847-b84e-4a60-8a5d-003e86c537f3' User entered 'No (N)'	System	01 Sep 2020 16:42:04
	System	01 Sep 2020 16:42:04

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-01T12:42:01', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '8405f847-b84e-4a60-8a5d-003e86c537f3' User entered '01 Sep 2020 12:42'	System	01 Sep 2020 16:42:04
	System	01 Sep 2020 16:42:04

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 18:47:08

US3122083

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 18:47:08

US3122083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:01:05

US3122083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '03 Sep 2020'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:01:05

US3122083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:01:05

US3122083

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:01:05

US3122083

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	04 Sep 2020 14:01:10

US3122083

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	04 Sep 2020 14:01:10

US3122083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:00

US3122083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:00

US3122083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:00

US3122083

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:00

US3122083

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:03

US3122083

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	11 Sep 2020 17:36:03

US3122083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:55:45

US3122083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '16 Sep 2020'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:55:45

US3122083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:55:45

US3122083

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:55:45

US3122083

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:55:57

US3122083

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	17 Sep 2020 17:55:57

US3122083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:28

US3122083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:28

US3122083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:28

US3122083

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'VISIT3'	System	30 Sep 2020 15:00:28

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered empty.	System	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered empty.	System	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered empty.	System	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered empty.	System	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered empty.	System	30 Sep 2020 15:00:47

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41

US3122083

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41

US3122083

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:01:20

US3122083

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:01:20

US3122083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:18

US3122083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:18

US3122083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '08:24'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:18

US3122083

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered '25 Sep 2020 08:24'	System	30 Sep 2020 15:00:18

US3122083

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:00:20

US3122083

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	30 Sep 2020 15:00:20

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 64'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-27T00:32:51', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '71bf2185-5958-4763-b1d2-f8490622e509' User entered 'No (N)'	System	27 Sep 2020 04:33:04
	System	27 Sep 2020 04:33:04

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-27T00:32:55', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '71bf2185-5958-4763-b1d2-f8490622e509' User entered 'No (N)'	System	27 Sep 2020 04:33:04
	System	27 Sep 2020 04:33:04

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-09-27T00:32:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '71bf2185-5958-4763-b1d2-f8490622e509' User entered '27 Sep 2020 00:32:59'	System	27 Sep 2020 04:33:04
	System	27 Sep 2020 04:33:04

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '27 Sep 2020 00:01'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '01 Oct 2020 23:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 71'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-04T09:19:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '15333c99-03d5-4474-af55-19a85715ed6b' User entered 'No (N)'	System	04 Oct 2020 13:19:54
	System	04 Oct 2020 13:19:54

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-04T09:19:46', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '15333c99-03d5-4474-af55-19a85715ed6b' User entered 'No (N)'	System	04 Oct 2020 13:19:54
	System	04 Oct 2020 13:19:54

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-04T09:19:52', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '15333c99-03d5-4474-af55-19a85715ed6b' User entered '04 Oct 2020 09:19:52'	System	04 Oct 2020 13:19:54
	System	04 Oct 2020 13:19:54

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '04 Oct 2020 00:01'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '08 Oct 2020 23:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 78'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-11T01:48:16', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'cfe0275b-7a86-4eac-815d-225fafee52a8' User entered 'No (N)'	System	11 Oct 2020 05:48:26
	System	11 Oct 2020 05:48:26

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-11T01:48:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'cfe0275b-7a86-4eac-815d-225fafee52a8'	System	11 Oct 2020 05:48:26
User entered 'No (N)'	System	11 Oct 2020 05:48:26

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-11T01:48:24', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'cfe0275b-7a86-4eac-815d-225fafee52a8' User entered '11 Oct 2020 01:48:24'	System	11 Oct 2020 05:48:26
	System	11 Oct 2020 05:48:26

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '11 Oct 2020 00:01'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '15 Oct 2020 23:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 92'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-25T00:10:17', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '36f7c798-385e-417a-ad23-4f62e9a8f74b' User entered 'No (N)'	System	25 Oct 2020 04:10:26
	System	25 Oct 2020 04:10:26

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-25T00:10:20', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '36f7c798-385e-417a-ad23-4f62e9a8f74b'	System	25 Oct 2020 04:10:26
User entered 'No (N)'	System	25 Oct 2020 04:10:26

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-10-25T00:10:25', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '36f7c798-385e-417a-ad23-4f62e9a8f74b' User entered '25 Oct 2020 00:10:25'	System	25 Oct 2020 04:10:26
	System	25 Oct 2020 04:10:26

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '25 Oct 2020 00:01'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '29 Oct 2020 23:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 99'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-01T00:02:31', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2da412af-9efc-469e-b1ae-b812c916ed52'	System	01 Nov 2020 04:02:44
User entered 'No (N)'	System	01 Nov 2020 04:02:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-01T00:02:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2da412af-9efc-469e-b1ae-b812c916ed52'	System	01 Nov 2020 04:02:44
User entered 'No (N)'	System	01 Nov 2020 04:02:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-01T00:02:38', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2da412af-9efc-469e-b1ae-b812c916ed52' User entered '01 Nov 2020 00:02:38'	System	01 Nov 2020 04:02:44
	System	01 Nov 2020 04:02:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '01 Nov 2020 00:01'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '05 Nov 2020 23:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 106'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-08T07:48:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'd8c2b811-fdb4-446b-9b00-52ef79ac44c5' User entered 'No (N)'	System	08 Nov 2020 12:48:46
	System	08 Nov 2020 12:48:46

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-08T07:48:40', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'd8c2b811-fdb4-446b-9b00-52ef79ac44c5' User entered 'No (N)'	System	08 Nov 2020 12:48:46
	System	08 Nov 2020 12:48:46

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-08T07:48:45', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'd8c2b811-fdb4-446b-9b00-52ef79ac44c5' User entered '08 Nov 2020 07:48:45'	System	08 Nov 2020 12:48:46
	System	08 Nov 2020 12:48:46

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '08 Nov 2020 00:01'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '12 Nov 2020 23:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered 'Day 113'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-15T00:05:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e3c31bde-7f50-4e2a-87e8-04bdee10d6db' User entered 'No (N)'	System	15 Nov 2020 05:05:29
	System	15 Nov 2020 05:05:29

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-15T00:05:21', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e3c31bde-7f50-4e2a-87e8-04bdee10d6db' User entered 'No (N)'	System	15 Nov 2020 05:05:29
	System	15 Nov 2020 05:05:29

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-11-15T00:05:25', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e3c31bde-7f50-4e2a-87e8-04bdee10d6db' User entered '15 Nov 2020 00:05:25'	System	15 Nov 2020 05:05:29
	System	15 Nov 2020 05:05:29

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '15 Nov 2020 00:01'	System	28 Jul 2020 22:45:44

US3122083

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:22:21
Data entry locked.	System	28 Jul 2020 22:45:44
User entered '19 Nov 2020 23:59'	System	28 Jul 2020 22:45:44

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-03T06:10:45', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e6d85b9a-be2a-4247-80eb-61c714701842' User entered 'No (N)'	System	03 Dec 2020 11:10:59
	System	03 Dec 2020 11:10:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-03T06:10:49', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e6d85b9a-be2a-4247-80eb-61c714701842'	System	03 Dec 2020 11:10:59
User entered 'No (N)'	System	03 Dec 2020 11:10:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-03T06:10:53', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'e6d85b9a-be2a-4247-80eb-61c714701842' User entered '03 Dec 2020 06:10:53'	System	03 Dec 2020 11:10:59
	System	03 Dec 2020 11:10:59

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-10T00:04:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9cd0f460-70c5-435b-936a-4e33fe62ec0e' User entered 'No (N)'	System	10 Dec 2020 05:05:08
	System	10 Dec 2020 05:05:08

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-10T00:04:46', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9cd0f460-70c5-435b-936a-4e33fe62ec0e' User entered 'No (N)'	System	10 Dec 2020 05:05:08
	System	10 Dec 2020 05:05:08

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-10T00:04:50', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9cd0f460-70c5-435b-936a-4e33fe62ec0e' User entered '10 Dec 2020 00:04:50'	System	10 Dec 2020 05:05:08
	System	10 Dec 2020 05:05:08

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-17T07:13:43', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '79fa331f-63ed-45dc-8471-a8b036435959' User entered 'No (N)'	System	17 Dec 2020 12:13:56
	System	17 Dec 2020 12:13:56

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-17T07:13:47', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '79fa331f-63ed-45dc-8471-a8b036435959' User entered 'No (N)'	System	17 Dec 2020 12:13:56
	System	17 Dec 2020 12:13:56

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-17T07:13:54', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '79fa331f-63ed-45dc-8471-a8b036435959' User entered '17 Dec 2020 07:13:54'	System	17 Dec 2020 12:13:56
	System	17 Dec 2020 12:13:56

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-24T00:01:16', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '031a71fb-9f04-4806-b657-171c64620dfb' User entered 'No (N)'	System	24 Dec 2020 05:01:30
	System	24 Dec 2020 05:01:30

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-24T00:01:20', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '031a71fb-9f04-4806-b657-171c64620dfb' User entered 'No (N)'	System	24 Dec 2020 05:01:30
	System	24 Dec 2020 05:01:30

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-24T00:01:23', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '031a71fb-9f04-4806-b657-171c64620dfb' User entered '24 Dec 2020 00:01:23'	System	24 Dec 2020 05:01:30
	System	24 Dec 2020 05:01:30

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-31T00:01:57', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e329335-c817-4b4f-8e27-0b45d4da1bab' User entered 'No (N)'	System	31 Dec 2020 05:02:17
	System	31 Dec 2020 05:02:17

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-31T00:01:59', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e329335-c817-4b4f-8e27-0b45d4da1bab' User entered 'No (N)'	System	31 Dec 2020 05:02:17
	System	31 Dec 2020 05:02:17

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2020-12-31T00:02:02', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0e329335-c817-4b4f-8e27-0b45d4da1bab' User entered '31 Dec 2020 00:02:02'	System	31 Dec 2020 05:02:17
	System	31 Dec 2020 05:02:17

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-07T08:51:33', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9feffc7b-554e-4c3a-b218-14c562c1998d' User entered 'No (N)'	System	07 Jan 2021 13:51:43
	System	07 Jan 2021 13:51:43

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-07T08:51:35', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9feffc7b-554e-4c3a-b218-14c562c1998d' User entered 'No (N)'	System	07 Jan 2021 13:51:43

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-07T08:51:38', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9feffc7b-554e-4c3a-b218-14c562c1998d' User entered '07 Jan 2021 08:51:38'	System	07 Jan 2021 13:51:43
	System	07 Jan 2021 13:51:43

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-14T00:01:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9f87051c-547f-4c9f-a6c9-15be64b7db6b'	System	14 Jan 2021 05:01:42
User entered 'No (N)'	System	14 Jan 2021 05:01:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-14T00:01:23', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9f87051c-547f-4c9f-a6c9-15be64b7db6b'	System	14 Jan 2021 05:01:42
User entered 'No (N)'	System	14 Jan 2021 05:01:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-14T00:01:27', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9f87051c-547f-4c9f-a6c9-15be64b7db6b' User entered '14 Jan 2021 00:01:27'	System	14 Jan 2021 05:01:42
	System	14 Jan 2021 05:01:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-21T00:01:28', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '620b5ebf-70d6-4793-9c10-86ece680ecdf' User entered 'No (N)'	System	21 Jan 2021 05:01:42
	System	21 Jan 2021 05:01:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-21T00:01:31', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '620b5ebf-70d6-4793-9c10-86ece680ecdf' User entered 'No (N)'	System	21 Jan 2021 05:01:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-21T00:01:36', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '620b5ebf-70d6-4793-9c10-86ece680ecdf' User entered '21 Jan 2021 00:01:36'	System	21 Jan 2021 05:01:42
	System	21 Jan 2021 05:01:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-28T00:01:19', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '17765875-e53d-4727-b467-7cca86dfcb64' User entered 'No (N)'	System	28 Jan 2021 05:01:51
	System	28 Jan 2021 05:01:51

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-28T00:01:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '17765875-e53d-4727-b467-7cca86dfcb64'	System	28 Jan 2021 05:01:51
User entered 'No (N)'	System	28 Jan 2021 05:01:51

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-01-28T00:01:25', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '17765875-e53d-4727-b467-7cca86dfcb64' User entered '28 Jan 2021 00:01:25'	System	28 Jan 2021 05:01:51
	System	28 Jan 2021 05:01:51

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-04T00:01:42', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '908fee31-d21a-4b18-b48a-98a122514987' User entered 'No (N)'	System	04 Feb 2021 05:02:14
	System	04 Feb 2021 05:02:14

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-04T00:01:45', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '908fee31-d21a-4b18-b48a-98a122514987' User entered 'No (N)'	System	04 Feb 2021 05:02:14
	System	04 Feb 2021 05:02:14

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-04T00:01:47', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '908fee31-d21a-4b18-b48a-98a122514987' User entered '04 Feb 2021 00:01:47'	System	04 Feb 2021 05:02:14
	System	04 Feb 2021 05:02:14

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-11T00:22:13', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'bc645e5c-b5d9-4150-9f51-1d49ffbf3434'	System	11 Feb 2021 05:22:25
User entered 'No (N)'	System	11 Feb 2021 05:22:25

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-11T00:22:17', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'bc645e5c-b5d9-4150-9f51-1d49ffbf3434'	System	11 Feb 2021 05:22:25
User entered 'No (N)'	System	11 Feb 2021 05:22:25

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-11T00:22:22', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'bc645e5c-b5d9-4150-9f51-1d49ffbf3434' User entered '11 Feb 2021 00:22:22'	System	11 Feb 2021 05:22:25
	System	11 Feb 2021 05:22:25

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-18T02:34:06', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a83a0e8a-64ac-492f-8bd2-b093fe58f96e' User entered 'No (N)'	System	18 Feb 2021 07:34:15
	System	18 Feb 2021 07:34:15

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-18T02:34:08', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a83a0e8a-64ac-492f-8bd2-b093fe58f96e'	System	18 Feb 2021 07:34:15
User entered 'No (N)'	System	18 Feb 2021 07:34:15

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-18T02:34:13', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a83a0e8a-64ac-492f-8bd2-b093fe58f96e'	System	18 Feb 2021 07:34:15
User entered '18 Feb 2021 02:34:13'	System	18 Feb 2021 07:34:15

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-25T00:22:20-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '419156cb-82e2-4796-871a-8a29e3ff7f35'	System	01 Mar 2021 17:57:42
User entered 'No (N)'	System	01 Mar 2021 17:57:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-25T00:22:23-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '419156cb-82e2-4796-871a-8a29e3ff7f35'	System	01 Mar 2021 17:57:42
User entered 'No (N)'	System	01 Mar 2021 17:57:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-02-25T00:22:27-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '419156cb-82e2-4796-871a-8a29e3ff7f35'	System	01 Mar 2021 17:57:42
User entered '25 Feb 2021 05:22:27'	System	01 Mar 2021 17:57:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-04T00:02:14-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0b1ec8d9-8252-410a-9753-3556ba7eaaa9'	System	04 Mar 2021 05:03:42
User entered 'No (N)'	System	04 Mar 2021 05:03:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-04T00:02:17-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0b1ec8d9-8252-410a-9753-3556ba7eaaa9'	System	04 Mar 2021 05:03:42
User entered 'No (N)'	System	04 Mar 2021 05:03:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-04T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '0b1ec8d9-8252-410a-9753-3556ba7eaaa9'	System	04 Mar 2021 05:03:42
User entered '04 Mar 2021 00:02:20'	System	04 Mar 2021 05:03:42

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-11T09:27:03-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2461e1aa-df6f-4f9e-a026-df331d9292ff'	System	14 Mar 2021 21:30:13
User entered 'No (N)'	System	14 Mar 2021 21:30:13

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-11T09:27:06-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2461e1aa-df6f-4f9e-a026-df331d9292ff' User entered 'No (N)'	System	14 Mar 2021 21:30:13

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-11T09:27:09-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2461e1aa-df6f-4f9e-a026-df331d9292ff' User entered '11 Mar 2021 09:27:09'	System	14 Mar 2021 21:30:13
	System	14 Mar 2021 21:30:13

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-18T17:49:09-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '72c8a322-474f-47f8-8c9a-61c582d81fd1'	System	18 Mar 2021 21:49:20
User entered 'No (N)'	System	18 Mar 2021 21:49:20

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-18T17:49:12-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '72c8a322-474f-47f8-8c9a-61c582d81fd1'	System	18 Mar 2021 21:49:20
User entered 'No (N)'	System	18 Mar 2021 21:49:20

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-18T17:49:16-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '72c8a322-474f-47f8-8c9a-61c582d81fd1'	System	18 Mar 2021 21:49:20
User entered '18 Mar 2021 17:49:16'	System	18 Mar 2021 21:49:20

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-25T01:42:36-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '99409ea6-dd21-4965-9e68-0fbc70909116'	System	25 Mar 2021 15:29:50
User entered 'No (N)'	System	25 Mar 2021 15:29:50

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-25T01:42:46-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '99409ea6-dd21-4965-9e68-0fbc70909116'	System	25 Mar 2021 15:29:50
User entered 'No (N)'	System	25 Mar 2021 15:29:50

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-25T01:43:03-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '99409ea6-dd21-4965-9e68-0fbc70909116' User entered '25 Mar 2021 01:43:03'	System	25 Mar 2021 15:29:50
	System	25 Mar 2021 15:29:50

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-01T00:36:02-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a5f738ad-86f7-4923-aec4-502216420cc4'	System	08 Apr 2021 01:41:39
User entered 'No (N)'	System	08 Apr 2021 01:41:39

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-01T00:36:07-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a5f738ad-86f7-4923-aec4-502216420cc4'	System	08 Apr 2021 01:41:39
User entered 'No (N)'	System	08 Apr 2021 01:41:39

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-01T00:36:10-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: 'a5f738ad-86f7-4923-aec4-502216420cc4'	System	08 Apr 2021 01:41:39
User entered '01 Apr 2021 00:36:10'	System	08 Apr 2021 01:41:39

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-08T06:10:42-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2ee8aec1-c996-4f5c-83bf-97e01790da5d'	System	08 Apr 2021 10:10:54
User entered 'No (N)'	System	08 Apr 2021 10:10:54

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-08T06:10:47-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2ee8aec1-c996-4f5c-83bf-97e01790da5d'	System	08 Apr 2021 10:10:54
User entered 'No (N)'	System	08 Apr 2021 10:10:54

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-08T06:10:52-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '2ee8aec1-c996-4f5c-83bf-97e01790da5d'	System	08 Apr 2021 10:10:54
User entered '08 Apr 2021 06:10:52'	System	08 Apr 2021 10:10:54

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-15T00:46:09-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '923b1a73-260f-44b1-825b-4e35555cfffaf' User entered 'No (N)'	System	15 Apr 2021 05:46:19
	System	15 Apr 2021 05:46:19

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-15T00:46:12-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '923b1a73-260f-44b1-825b-4e35555cfffaf' User entered 'No (N)'	System	15 Apr 2021 05:46:19
	System	15 Apr 2021 05:46:19

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-15T00:46:16-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '923b1a73-260f-44b1-825b-4e35555cfffaf'	System	15 Apr 2021 05:46:19
User entered '15 Apr 2021 00:46:16'	System	15 Apr 2021 05:46:19

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-22T00:10:16-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9be7e18f-9158-4ca9-81c4-bb3752cf6153'	System	22 Apr 2021 04:10:27
User entered 'No (N)'	System	22 Apr 2021 04:10:27

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-22T00:10:21-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9be7e18f-9158-4ca9-81c4-bb3752cf6153'	System	22 Apr 2021 04:10:27
User entered 'No (N)'	System	22 Apr 2021 04:10:27

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-22T00:10:24-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '9be7e18f-9158-4ca9-81c4-bb3752cf6153'	System	22 Apr 2021 04:10:27
User entered '22 Apr 2021 00:10:24'	System	22 Apr 2021 04:10:27

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-29T00:12:23-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '4fbb2190-d579-4c9c-abd3-9093abc71a5b' User entered 'No (N)'	System	29 Apr 2021 04:12:32
	System	29 Apr 2021 04:12:32

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-29T00:12:26-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '4fbb2190-d579-4c9c-abd3-9093abc71a5b' User entered 'No (N)'	System	29 Apr 2021 04:12:32

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-04-29T00:12:29-04:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '4fbb2190-d579-4c9c-abd3-9093abc71a5b' User entered '29 Apr 2021 00:12:29'	System	29 Apr 2021 04:12:32
	System	29 Apr 2021 04:12:32

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 02:30:41

US3122083

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:30:41
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 02:30:41

US3122083

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:21:06

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-01T12:57:48-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '6a217fa5-65d9-476f-9f04-892813865540'	System	01 Mar 2021 17:58:15
User entered 'Yes (Y)'	System	01 Mar 2021 17:58:15

US3122083

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:21:06

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-01T12:57:55-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '6a217fa5-65d9-476f-9f04-892813865540' User entered 'No (N)'	System	01 Mar 2021 17:58:15
	System	01 Mar 2021 17:58:15

US3122083

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:21:06

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6F6B120-D247-405E-B9B3-1650ACA50DF6)', Time: '2021-03-01T12:58:03-05:00', User OID: 'PatientReportedOutcome (US3122083)', ODM File OID: '6a217fa5-65d9-476f-9f04-892813865540' User entered '01 Mar 2021 12:58:03'	System	01 Mar 2021 17:58:15
	System	01 Mar 2021 17:58:15

US3122083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:08:22

US3122083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:08:22

US3122083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:08:22

US3122083

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:08:22

US3122083

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:08:26

US3122083

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:50:41
User entered 'I'	System	17 Nov 2020 13:08:26

US3122083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:09:15

US3122083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:09:15

US3122083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:09:15

US3122083

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Patient was initially contacted 12Nov2020 but requested later call'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:09:15

US3122083

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:09:20

US3122083

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User entered 'I'	System	17 Nov 2020 13:09:20

US3122083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:29:36

US3122083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:40:06
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Contact out of window due to holiday' (Site from System).	(b) (4), (b) (6)	04 Jan 2021 16:50:34
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	31 Dec 2020 19:29:36
User entered '31 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 19:29:36

US3122083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:29:36

US3122083

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:29:36

US3122083

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:29:42

US3122083

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User entered 'I'	System	31 Dec 2020 19:29:42

US3122083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:22

US3122083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:22

US3122083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:22

US3122083

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:22

US3122083

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:27

US3122083

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User entered 'I'	System	21 Jan 2021 21:36:27

US3122083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 10FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).		31 Mar 2021 20:17:51
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 10FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, the the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate answered with 'updated' (Site from DM).		30 Mar 2021 13:27:24
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 10FEB2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).		30 Mar 2021 06:23:04
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:54:15

US3122083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:54:15

US3122083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:54:15

US3122083

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User entered 'VISIT4'	System	15 Mar 2021 18:54:15

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered '09:40'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User entered '10 Feb 2021 09:40'	System	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered '36.0' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered '63'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User entered 'bpm'	System	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered '12'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User entered 'breaths/min'	System	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered '125'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User entered 'mmHg'	System	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	30 Mar 2021 13:54:53
User entered '75'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User entered 'mmHg'	System	30 Mar 2021 13:27:17

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24

US3122083

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24

US3122083

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:54:27

US3122083

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:54:27

US3122083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:55:59

US3122083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:55:59

US3122083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:55:59

US3122083

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:24
User entered empty.	System	15 Mar 2021 18:55:59

US3122083

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:56:03

US3122083

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:13:21
User entered 'I'	System	15 Mar 2021 18:56:03

US3122083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:49
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:35:29

US3122083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:49
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:04
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:35:29

US3122083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:49
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:35:29

US3122083

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:49
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:04
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:35:29

US3122083

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:49
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:31:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:35:35

US3122083

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:49
User entered 'I'	System	24 Mar 2021 12:35:35

US3122083

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:05:54

US3122083

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:05:54

US3122083

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:05:54

US3122083

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:05:54

US3122083

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:05:59

US3122083

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 19:05:59

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:29

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:29

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:29

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 16:20:29

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:59:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:41:53

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:59:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:41:53

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 05:39:37
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 05:39:37
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '1'	System	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'I'	System	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered empty.	System	12 Jan 2021 16:22:45
DataPoint set to visible.	System	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered empty.	System	12 Jan 2021 16:22:45
DataPoint set to visible.	System	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User accepted default value 'Pre-Dose (PREDOSE)'		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '10:20'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '12 Jan 2021 10:20'	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 06:24:20
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'		15 Mar 2021 19:01:37
answered with 'Not Clinically Significant as per source indication.' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Jan 2021 16:22:45
User entered '95.1' F	(b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '63'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'bpm'	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '14'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'breaths/min'	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '130'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mmHg'	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '85'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mmHg'	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered empty.	System	12 Jan 2021 16:22:45
DataPoint set to visible.	System	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User accepted default value 'Post-Dose (POSTDOSE)'		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 17:55:18
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 17:55:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 16:22:45
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '12 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 17:55:18
User entered empty.		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '11:37' reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 17:55:18
User entered empty.		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '12 Jan 2021 11:37'	System	12 Jan 2021 17:55:18
User entered empty.	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '98.1' F reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 17:55:18
User entered empty.		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Oral (Oral)' reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 17:55:18
User entered empty.		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '61' reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 17:55:18
User entered empty.		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'bpm'	System	12 Jan 2021 17:55:18
User entered empty.	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '16' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:55:18
User entered empty.		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'breaths/min'	System	12 Jan 2021 17:55:18
User entered empty.	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '130' reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 17:55:18
User entered empty.		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mmHg'	System	12 Jan 2021 17:55:18
User entered empty.	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '97' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:55:18
User entered empty.		12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mmHg'	System	12 Jan 2021 17:55:18
User entered empty.	System	12 Jan 2021 16:22:45

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:23:13

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:23:13

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mRNA-1273'	System	12 Jan 2021 16:21:15
DataPoint set to visible.	System	12 Jan 2021 16:20:51

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10:59'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '12 Jan 2021 10:59'	System	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'ONCE'	System	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 16:21:15

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:53:19

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:53:19

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10:51'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:53:19

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '12 Jan 2021 10:51'	System	12 Jan 2021 17:53:19

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:53:32

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:53:32

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:21:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10:54'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:53:32

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:21:06

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '12 Jan 2021 10:54'	System	12 Jan 2021 17:53:32

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:53:40

US3122083

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'I'	System	12 Jan 2021 17:53:40

US3122083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:02

US3122083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:02

US3122083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:02

US3122083

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:02

US3122083

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:36:07

US3122083

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'I'	System	21 Jan 2021 21:36:07

US3122083

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'I'	System	21 Jan 2021 21:36:07
DataPoint set to visible.	System	21 Jan 2021 21:36:07

US3122083

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:34

US3122083

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:34

US3122083

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:34

US3122083

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'OLD29'	System	10 Feb 2021 16:13:34

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User accepted default value 'Pre-Dose (PREDOSE)'		10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '09:40'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '10 Feb 2021 09:40'	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '36.0' C	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '63'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'bpm'	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '12'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'breaths/min'	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '125'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mmHg'	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '75'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mmHg'	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User accepted default value 'Post-Dose (POSTDOSE)'		10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered empty.	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered empty.	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered empty.	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered empty.	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered empty.	System	10 Feb 2021 16:15:06

US3122083

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:52

US3122083

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:13:52

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mRNA-1273'	System	10 Feb 2021 16:15:24
DataPoint set to visible.	System	21 Jan 2021 21:36:07

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '10:29'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '10 Feb 2021 10:29'	System	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'ONCE'	System	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 16:15:24

US3122083

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:15:29

US3122083

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'I'	System	10 Feb 2021 16:15:29

US3122083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:03:38

US3122083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:03:38

US3122083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:03:38

US3122083

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:03:38

US3122083

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:03:43

US3122083

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'I'	System	17 Feb 2021 15:03:43

US3122083

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:39:34

US3122083

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:39:34

US3122083

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:39:34

US3122083

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'OLD57'	System	15 Mar 2021 18:39:34

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '09:05'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '15 Mar 2021 09:05'	System	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	15 Mar 2021 18:41:18
User entered '36.4' C reason for change: Data Entry Error	System	15 Mar 2021 18:41:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 18:41:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Mar 2021 18:41:08
User entered '36.' (non-conformant).	System	15 Mar 2021 18:41:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 18:41:08
User entered '36.' (non-conformant).	System	15 Mar 2021 18:40:01
User entered '36.' (non-conformant).	System	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 18:41:24
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	15 Mar 2021 18:41:24
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:41:24
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Mar 2021 18:41:18
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Mar 2021 18:41:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 18:41:08
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:41:08
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Mar 2021 18:40:01
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'bpm'	System	15 Mar 2021 18:41:08
User entered empty.	System	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Mar 2021 18:41:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 18:41:08
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:41:08
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Mar 2021 18:40:01
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'breaths/min'	System	15 Mar 2021 18:41:08
User entered empty.	System	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	15 Mar 2021 18:41:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 18:41:08
User entered '150' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:41:08
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Mar 2021 18:40:01
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mmHg'	System	15 Mar 2021 18:41:08
User entered empty.	System	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 18:41:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 18:41:08
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:41:08
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Mar 2021 18:40:01
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered 'mmHg'	System	15 Mar 2021 18:41:08
User entered empty.	System	15 Mar 2021 18:40:01

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19

US3122083

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19

US3122083

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:41:35

US3122083

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:41:35

US3122083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:52:47

US3122083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:52:47

US3122083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User signature succeeded.	Matthew Hong (b) (4)	16 Mar 2021 18:58:02
User entered '09:10'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 18:52:47

US3122083

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:35:19
User entered '15 Mar 2021 09:10'	System	15 Mar 2021 18:52:47

US3122083

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:21:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:46:10
User signature succeeded.	Matthew Hong (b) (4)	14 Apr 2021 19:41:42
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:09:06
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).		12 Apr 2021 20:04:28
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		09 Feb 2021 02:02:07
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	17 Sep 2020 17:48:27

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:51:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:51:36
Data point term sent to Coder	System	17 Sep 2020 17:50:12
User entered 'Sinus Infection'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:03:19
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'Corrected' (Site from DM).	Leah Corts (b) (4)	08 Oct 2020 16:36:16
User entered 'No (N)' reason for change: Data Entry Error	Leah Corts (b) (4)	08 Oct 2020 16:35:54
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:15:21
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '18 Aug 2020'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User entered empty.	System	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '20 Aug 2020'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User entered empty.	System	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Not Related (NOT RELATED)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Not Related (NOT RELATED)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'None (NONE)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the Concomitant Procedure recorded was after the stop date of this AE. Please review and reconcile AE and CP start date as appropriate or update action taken.' (Site from DM).	(b) (4)	16 Oct 2020 16:04:18
Query 'Per DM CLR: Other Action Taken = Con Proc, however the Concomitant Procedure recorded was after the stop date of this AE. Please review and reconcile AE and CP start date as appropriate or update action taken.' answered with 'Corrected' (Site from DM).	Leah Corts (b) (4)	13 Oct 2020 19:31:23
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the Concomitant Procedure recorded was after the stop date of this AE. Please review and reconcile AE and CP start date as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:15:30
User entered 'I'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	Brad Killebrew (b) (4)	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User entered '0'	System	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58
User entered '0'	System	17 Sep 2020 17:49:36

US3122083

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:37:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:21:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:21:12
Data point term sent to Coder	System	12 Apr 2021 20:04:34
User entered 'Fatigue'	(b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '00:00'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User entered '29 Jul 2020 00:00'	System	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '05 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '23:59'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User entered '05 Aug 2020 23:59'	System	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User signature succeeded.	Matthew Hong (b) (4)	13 Apr 2021 18:00:42
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User entered '0'	System	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01
User entered '0'	System	12 Apr 2021 20:03:52

US3122083

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:01

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:31
User entered 'USA-US063-2021-mRNA-1273-P301000003'	System	26 Apr 2021 16:42:19
User entered 'New'	(b) (4), (b) (6)	26 Apr 2021 16:42:19

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Anaphylactic and anaphylactoid responses, PT: Anaphylactic reaction, LLT: Anaphylactic reaction to drug - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:41:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:41:51
Data point term sent to Coder	System	23 Apr 2021 16:20:36
User entered 'anaphylactic reaction to Steroid Shot'	(b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:40:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 16:40:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 16:40:35
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:19:56
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	23 Apr 2021 16:40:35
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Apr 2021 16:19:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '1' reason for change: Data Entry Error	(b) (4)	23 Apr 2021 16:40:35
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '1' reason for change: Data Entry Error	(b) (4)	23 Apr 2021 16:40:35
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please specify the reason/medical condition why the subject required the steroid injection in right arm. ' (Site from Safety)	(b) (4), (b) (6)	03 May 2021 12:17:07
User opened query 'PV Query: Please specify the steroid which caused the anaphylactic reaction. ' (Site from Safety).		03 May 2021 12:17:01
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:19:56

US3122083

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:21:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:19:56

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:21:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:46:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:48:34

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 19:18:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 19:18:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 19:17:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 19:17:38
Data point term sent to Coder	System	28 Aug 2020 19:17:20
User closed query 'For coding purposes, Please enter the active ingredient(s) in parenthesis after drug name or specify if unknown, and please make your changes to the reported term.' (Site from System).	System	28 Aug 2020 19:16:19
Query 'For coding purposes, Please enter the active ingredient(s) in parenthesis after drug name or specify if unknown, and please make your changes to the reported term.' answered with 'Clarified' (Site from System).	Leah Cortis (b) (4)	28 Aug 2020 19:16:19
Data point term sent to Coder	System	28 Aug 2020 19:16:18
User entered 'Allegra' reason for change: Data Entry Error	Leah Cortis (b) (4)	28 Aug 2020 19:16:08

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, Please enter the active ingredient(s) in parenthesis after drug name or specify if unknown, and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	03 Aug 2020 13:45:57
Data point term sent to Coder	System	31 Jul 2020 17:52:20
User entered 'Allergy Pill'	Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Seasonal Allergies'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:35:58
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	17 Sep 2020 17:55:12
User entered '180' reason for change: Data Entry Error	Brad Killebrew (b) (4)	17 Sep 2020 17:55:01
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 06:09:15
User entered '1'	Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Brad Killebrew (b) (4)	17 Sep 2020 17:55:08
User entered 'tablet (TABLET)'	Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4)	
	Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'once daily (QD)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (ORAL)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:04:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brad Killebrew (b) (4)	31 Jul 2020 17:51:45
answered with 'Correct as is ' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 17:51:38
User entered 'un UNK 2015'	Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4)	
	Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 17:51:38

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Jul 2020 17:54:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Jul 2020 17:54:07
Data point term sent to Coder	System	31 Jul 2020 17:53:20
User entered 'Citalopram'	Brad Killebrew (b) (4) (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Depression'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '20'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'mg (mg)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'once daily (QD)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (ORAL)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as is ' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 14:04:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 17:53:12
User entered 'un Jun 2019'	System	31 Jul 2020 17:53:06
	Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 17:53:06

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Jul 2020 17:56:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 17:56:08
Data point term sent to Coder	System	31 Jul 2020 17:55:21
User entered 'Vitamin D'	Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Supplement'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '5000'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'IU (IU)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'once daily (QD)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (ORAL)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:04:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brad Killebrew (b) (4)	31 Jul 2020 17:54:31
answered with 'Correct as is ' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 17:54:26
User entered 'un Mar 2020'	Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '0'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 17:54:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:54:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:54:45
Data point term sent to Coder Coding entries removed.	System Brad Killebrew (b) (4)	17 Sep 2020 17:54:24 17 Sep 2020 17:54:07
User entered 'ADVAIR 100/50' reason for change: Data Entry Error	Brad Killebrew (b) (4)	17 Sep 2020 17:54:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 17:57:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 17:57:13
Data point term sent to Coder	System	31 Jul 2020 17:56:21
User entered 'Advair'	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Asthma'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:36:20
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. answered with 'added to name' (Site from DM).	Brad Killebrew (b) (4)	17 Sep 2020 17:54:13
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 06:08:10
User entered 'I'	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'puff (PUFF)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'as needed (PRN)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct as is ' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 14:04:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Brad Killebrew (b) (4)	31 Jul 2020 17:56:25
User entered 'un UNK 2002'	System	31 Jul 2020 17:56:19
	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 17:56:19

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL HYDROCHLORIDE, PRODUCTSYNONYM: XOPENEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 13:56:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 13:56:16
Data point term sent to Coder	System	31 Jul 2020 17:58:22
User entered 'Xopenex'	Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'No (N)'	Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'Asthma'	Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '1'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'puff (PUFF)'	Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'as needed (PRN)'	Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Aug 2020 14:05:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brad Killebrew (b) (4)	31 Jul 2020 17:57:31
answered with 'Correct as is ' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 17:57:26
User entered 'un UNK 2016'	Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered '0'	Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Brad Killebrew (b) (4)	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 17:57:26

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 16:55:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 16:55:22
Data point term sent to Coder	System	19 Aug 2020 16:54:42
User entered 'valtrex'	Aubrey Farrey (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'No (N)'	Aubrey Farrah (b) (4)	19 Aug 2020 16:54:02
	(b) (4)	

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:37:09
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	17 Sep 2020 17:53:24
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 06:09:36
User entered 'Herpes Type 2'	Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered '500'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'mg (mg)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Aubrey Farrah (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'twice daily (BID)'	Aubrey Farray (b) (4)	19 Aug 2020 16:54:02
	(b) (4)	

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Oral (ORAL)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Aubrey Farrah (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:09:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:54:02
User entered 'UN UNK 2010'	Aubrey Farray (b) (4)	19 Aug 2020 16:54:02
	(b) (4)	

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered '0'	Aubrey Farray (b) (4)	19 Aug 2020 16:54:02
	(b) (4)	

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'Yes (Y)'	Aubrey Farray (b) (4)	19 Aug 2020 16:54:02
	(b) (4)	

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered empty.	(b) (4) Aubrey Farrah (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'No (N)'	(b) (4) Aubrey Farray (b) (4) (b) (4)	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 16:54:02

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:53:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:52:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:52:43
Data point term sent to Coder	System	17 Sep 2020 17:51:14
Query 'Per DM CLR: Please provide brand name if known. ' answered with 'unknown' (Site from DM).	Brad Killebrew (b) (4)	17 Sep 2020 17:51:06
Coding entries removed.	Brad Killebrew (b) (4)	17 Sep 2020 17:51:01
User entered 'MULTIVItAMIN' reason for change: Data Entry Error	Brad Killebrew (b) (4)	17 Sep 2020 17:51:01
User opened query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 08:50:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 07:33:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 07:33:36
Data point term sent to Coder	System	28 Aug 2020 19:31:46
User entered 'Multiviatmin'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'Supplement'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered '2'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'tablet (TABLET)'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'once daily (QD)'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'Oral (ORAL)'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered '19 Aug 2020'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'Yes (Y)'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 19:31:13

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Mar 2021 16:25:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:25:50
Data point term sent to Coder	System	11 Mar 2021 15:59:19
User entered 'Botox'	(b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered 'Cosmetic injections'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered '25' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:00:14
User entered 'Unknown'		11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:00:14
User entered 'Other (OTHER)'		11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:00:14
User entered 'Unknown'		11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User entered empty.	System	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User entered empty.	System	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:21:35
User entered empty.	System	11 Mar 2021 15:58:20

US3122083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:21:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:46:10
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Yes (Y)'	Brad Killebrew (b) (4)	17 Sep 2020 17:50:11

US3122083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:21:06

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User closed query 'Per DM: The date of Concomitant Procedure is after the stop date of Adverse Event. please Reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 07:55:48
Query 'Per DM: The date of Concomitant Procedure is after the stop date of Adverse Event. please Reconcile. ' answered with 'Corrected' (Site from DM).	Leah Corts (b) (4)	13 Oct 2020 19:30:52
User entered '18 Aug 2020' reason for change: Data Entry Error	Leah Corts (b) (4)	13 Oct 2020 19:30:43
User opened query 'Per DM: The date of Concomitant Procedure is after the stop date of Adverse Event. please Reconcile. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:03:44
User entered '28 Aug 2020'	Brad Killebrew (b) (4)	17 Sep 2020 17:50:37

US3122083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:21:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Subject used Neti Pot for treatment of sinus infection'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:50:37

US3122083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:21:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
User entered 'Adverse Event (AE)'	(b) (4) Brad Killebrew (b) (4)	17 Sep 2020 17:50:37

US3122083

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:21:06

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:54:09
	(b) (4)	
User entered empty.	Brad Killebrew (b) (4)	17 Sep 2020 17:50:37

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'USA-US063-2021-MRNA-1273-P301000003'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Yes (Y)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'No (N)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Yes (Y)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'No (N)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'No (N)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'No (N)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Yes (Y)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Wayne'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Harper'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered '3100 Duraleigh Rd'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Raleigh'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'NC'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered '27612'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
User entered 'US'	(b) (4) System	26 Apr 2021 16:42:49

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 16:42:49

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'USA-US063-2021-MRNA-1273-P301000003'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Yes (Y)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

Death

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'No (N)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Yes (Y)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'No (N)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'No (N)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'No (N)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Yes (Y)'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Wayne'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Harper'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered '3100 Duraleigh Rd'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'Raleigh'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered 'NC'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:43
User entered '27612'	System	26 Apr 2021 16:42:19

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
User entered 'US'	(b) (4) System	26 Apr 2021 16:42:49

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 16:42:49

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:21:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
User entered '26/Apr/2021 12:42'	(b) (4) System	26 Apr 2021 16:42:49

US3122083

Folder: SAE USA-US063-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:21:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 16:57:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:42:49